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OFFICE OF PESTICIDE PROGRAMS' PRELIMINARY EVALUATION OF THE NONDIETARY HAZARD AND EXPOSURE TO CHILDREN FROM CONTACT WITH CHROMATED COPPER ARSENATE (CCA)-TREATED WOOD PLAYGROUND STRUCTURES AND CCA-CONTAMINATED SOIL

October 25, 2001

[12:30 p.m.]

Sheraton Crystal City Hotel
1800 Jefferson Davis Highway
Arlington, Virginia 22201

P A R T I C I P A N T S

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Xianglin Shi, Ph.D.

Andrew Smith, SM, ScD.

Helena Solo-Gabriele, Ph.D., P.E.

Jacob J. Steinberg, M.D.

Miroslav Styblo, Ph.D.

John Wargo, Ph.D.

DR. ROBERTS: Dr. Lees, I have you down as first off on this one. Would you start the discussion.

DR. LEES: I'll be happy to.

Actually, I had -- I'll try to be as concise as possible, and I had two major points that I wanted to make. Essentially we covered the first point in the proceeding discussion. So I'd like to proceed directly to the question of this .5 milligram per kilogram per day NOAEL and the evidence, the study, that was used to support that.

First of all, this should be an interesting presentation because I'm essentially a nontoxicologist reviewing a tox study so bear with me.

The study that has been used by the Agency for the purpose of the NOAEL for the short and intermediate oral exposure is actually the same study that they used for the assessment risks, that is, the study by Tile (ph), that's 1991.

And just very, very briefly what this is is a study of rabbits in which they were exposed to chromic acid via a bolus by gavage, a bolus of essentially chromic acid. And these were pregnant rabbits. As I said, that the primary purpose was to look at the developmental things.

In any event, there was a series of dose ranges, the highest dose of 5 milligrams per kilogram per day. This involved -- as I said, these were chromic acid in distilled water, so it wasn't buffered at all. And the resulting material that was gavaged had a pH of 1.5 in the highest dose.

This continued, I think it was a 12-day-dosing regime. The effects that were noted in the two high doses were, first of all, mortality; and in the highest dose, reduced weight gain; the highest dose diarrhea; and labored breathing, I think, was the other thing that was mentioned.

There was no pathology. You know the animals were autopsied at the end of the thing, and there was no pathology noted in any of these animals. Again, as a nontoxicologist here, I have great difficulty differentiating or attributing, if you will, the effects noted here to chromium as opposed to just the plain old acid effect.

And I would defer to my toxicology colleagues on the panel. I guess I wouldn't be surprised if this were -- well, we'll have a discussion on whether this is a chromium effect or an acid affect.

Having said that, there is a supporting study that is cited by the Agency, one from China by Tseng and Lee, which there is a

population that was exposed to drinking water; and it had a chromium concentration. And it's not really clear whether it was hexavalent or trivalent of some mixture of 20 milligrams per liter. Now the suggestion is that it is hexavalent.

And in this case, the exposure, or the dose, would be on the order of about .6 milligrams per kilogram per day. And there were -- there were -- the effects that were noted there were sores in the mouth, digestive, you know, vomiting, diarrhea, and those kinds of things for the most part.

So I guess the bottom line is that the Tile study, the main one that's cited to substantiate this .5 level, I have serious questions about whether it demonstrates what they actually say it demonstrates.

DR. ROBERTS: Okay. So...

DR. LEES: So I guess maybe we should first have a discussion of whether it does demonstrate what it say. And if it does not, as I suspect, then there has to be -- and I'm not familiar with it, the animal literature. But it seems to me there has to be some more appropriate. You know, instead of this bolus gavage, some dietary study or something like that that might be more appropriately used to establish this value.

DR. ROBERTS: Dr. Lees is expressing a lot of concern about the basis for this value and, therefore, the value itself, the reliability of the value itself.

DR. LEES: Yes, yes.

DR. ROBERTS: Dr. Shi, do you endorse that NOAEL, yes or no? And if so, why?

DR. SHI: I'll just give you several comments first. And my first concern is, my first point is, this question is very related to the last one. And the chromium III and the chromium VI issue is the bigger question here. And this is the first.

And the second issue is regarding here we talk about as an oral intake not the inhalation. So oral intake of chromium is not that bad because they can be reduced in the stomach for example. So for oral intake, you have a higher tolerance.

And the number of 0.5 milligram per kilogram per day, it looks like that number comes from two studies. One is the study for the rabbit that Dr. Lees just mentioned. Another is for the Chinese population in the drinking water.

And if you look at the animal study, they use chromium acid. And Dr. Lees raised the issue of that this may be an acid issue or a may be a chromium issue. And the dose that they use is from 0.1

to 5.0 milligram per kilogram per day. And this is a very small amount just for -- it's the first.

Second is the chromium acid is not a very strong acid. It did appear to be noted very low.

So I think that the pH may not be a big issue. And they use about a 10 times than the one used here. And they already observe some kind of effect, the diarrhea or something.

And, also, another study they use the from 2 to 5 milligram per kilogram per day dose. And it look like Brazille (ph) or some tests. So from that, 0.5 milligram seem a little better to have in my opinion.

And for the Chinese population study, as Dr. Lees mentioned, they have two concerns. One is we don't know if this is chromium VI or chromium III. But this says it's chromium VI. And in the -- but it is pretty hard to believe this is all chromium VI.

And second, it leads to another -- lead to tell exactly how much of the dose even though the admission is 70 kilogram of body weight. But that remains a lot of questions there.

And I feel to answer the question directly, I think that 0.5 just assume most of the chromium III they may be all right. But if

you consider the ratio between chromium VI and chromium III, it's unknown. So I think it should be a little bit of a decrease. But I have no idea how much it should decrease.

DR. ROBERTS: Okay. Dr. Styblo, I believe you are the next discussant on this.

DR. STYBLO: I'm on this minipanel by mistake. I'm not a chromium expert. I consider myself more into metalloids. So I won't waste your time.

I just want to bring one general issue here. We discuss speciation of chromium III, chromium VI; that's fine. That's important. We need more data. Again, this is not only the issue of speciation of chromium. We're talking about coexposure to other metals.

I had EPA staff to distribute some papers to you, some in vitro -- I mean, subcultures and some in vitro acute experiments. I understand they are not completely irrelevant to this issue, but they show clearly how important it is to consider coexposure because each component of the mixture makes a huge difference in the final toxicological outcome. We don't know at this time how relevant it is in the case of CCA, how relevant it is in the case of chronic exposure.

I would suggest to use conservative values, and I would recommend strongly that the Agency initiates studies that would come with the real data using samples that are relevant in terms of the chemical composition.

DR. ROBERTS: I think, certainly, we can comment on the weakness of the overall data base to allow the Agency to come up with this, to reach a decision. And maybe that's something we can all agree on.

I'm also hearing that there is some discomfort, at least in the opinions that have been expressed today, or so far a reluctance to endorse the NOAEL or at least the basis for the NOAEL. Are there any other comments from panel members on this? Dr. Mushak.

DR. MUSHAK: Yeah. Regarding Dr. Lees's comment about we're perhaps looking at an acid-induced injury artifact versus chromium VI; and, also, is there preservation of chromium VI in the biochemical sequence.

With rabbits, you have to be careful because even with short-term fasting -- there's a paper I've cited, and I'll send you the paper that's in my 1998 paper in EHP showing that you have to be careful with rabbits. You have to really allow a long fasting time. If you don't do that, then there's enough material around to

essentially slurp up acid. So even if you have an acid bolus, it may be simply consumed. So I think that would tend to rule out the acid explanation.

The second one has to deal with the business of if, in fact, you get quick conversion without any systemic or other effects, trivalent chromium feeding studies should be indistinguishable from hexavalent chromium feeding studies. And I don't think that occurs. I think this particular study shows more toxicity. Otherwise, you know, why did we do what we did in Question 4?

DR. ROBERTS: Okay. Does anyone want to weigh in on the no-effect level? Does anyone want to -- let met just ask for more comments. I'm not getting a real strong response from the Panel other than some uneasiness with this NOAEL; is that fair to say? Dr. Clewell.

DR. CLEWELL: I can't remember the last NOAEL I was easy with. That's the nature of the literature, I assure you, particularly for something that is essentially not very toxic chromium by the oral route. It's not very toxic so it's not an interesting chemical so it's going to be a weak data base forever.

DR. ROBERTS: Dr. Shi.

DR. SHI: If the definition of oral, I think that number

should be okay because is not that bad for oral intake of chromium.

DR. ROBERTS: I believe that that is a route-specific value, so it would be a value that would be applied to oral exposure.

Well, I guess I'm a little puzzled. Is there any recommendation from the Panel not to use -- oh, Dr. Vu.

DR. VU: I just want to clarify, again, what we're asking you all. We are proposing that the oral data base should be used to look at chromium exposure from CCA because of the ingestion route which is by soil contaminant chromium. And we all agree that chromium VI is the way that, if you don't have the data, we would conservatively use that.

In the document, we describe three studies of chromium VI through oral route. The rabbit study, the Tile study, which you all have recognized the limitation of Dr. Lees's question about where the chromium acid may contribute to the maternal toxicity. It has nothing to do with chromium per se of the pH. And Shi has a different view on that.

The other study we have is the rat study, a one-year study, which provides you a NOAEL of 2 milligram per kilogram per day.

And then you have the Tseng and Lee study, which is a study in human population, and you don't really have a NOAEL. You

have some, roughly 6 milligram per kilogram per day.

The Office of the Pesticide Program reviewed the three available studies and felt that, despite all those things, the rabbit study is probably best because we're looking at the intermediate short term. The rat study is more one-year study, and that's why they picked this thing. And we know there's limitation of data base, but we do the best that we can. And given that, we would like to get your recommendation. Thank you.

DR. ROBERTS: Thank you, Dr. Vu. With that clarification, Dr. Clewell.

DR. CLEWELL: I concur with the Agency's evaluation. I feel that's the right study to use, too.

DR. ROBERTS: All right. Dr. Mushak.

DR. MUSHAK: Yeah, I think before I'm convinced that there should be unease with this or the comfort levels should be dropped. You know, I would want to be convinced that, in fact, there is something about this that is seriously flawed. I've given you one rationale where the acid aspect probably is a no explanation. I mean, is there a real toxicological reason why there is a problem with this study other than maybe an artifact of acid?

DR. LEES: I was speaking as a nontoxicologist. And I was

really simply raising the question to the Panel with expertise beyond my own.

DR. ROBERTS: Let me propose, then, that the Panel would recommend or endorse the no-effect level, noting the limited data that the Agency had available to work with to come up with this value. Would that be a reasonable response? Dr. Ginsberg.

DR. GINSBERG: It appears to me that a concern with the Tile study is that they really didn't get any fetal toxicity through 5 milligram per kilogram per day doses which were really toxic to the mother. And the effects seen in the mother don't make it clear, a hundred percent clear, that there was good systemic exposure.

I mean, there was mortality. There was -- you know, chromic acid is going to be very, I would think, fairy reactive and toxic to contact sites. And it's just not clear from this study, given that there was no fetal effect level, that this is a good test with this chemical and this design.

You know, in contrast, there was this other paper which I've just been trying to catch up on by Mason who shows that sodium dichromate in the rat, 1 gavage dose on Day 8 of exposure, produced mild fetal toxic effects. So it's a different form of chromium, still chromium VI. And there is an effect level at a

dose level where rat versus rabbit. A lot of times rabbits are more sensitive in triogenicity studies than rats.

So I'm a little surprised that the Tile study didn't show anything, given that chromium apparently has some effect in rats at a comparable dose. So I'd be a little concerned about just relying totally on the Tile study.

VOICE: Can I comment on that?

DR. CLEWELL: What was the rat dose?

DR. ROBERTS: Wait, wait, wait.

DR. GINSBERG: 2.6.

DR. ROBERTS: I don't know that they're relying -- again, this is one of the situations totally on --

DR. GINSBERG: As the primary study.

DR. ROBERTS: It is the primary study. Dr. Gordon, and then, who else wanted to speak?

DR. GORDON: I was just going to comment. As a toxicologist, yeah, giving the material which is going to create a strong acid of pH 15 or 2, not putting it in a buffer solution for the treatment, is a big negative in interpreting this study. And in a repro study, though I'm not a reprotox guy, I'm pretty sure that if there is maternal toxicity, they always go down in dose because

they know they can't trust that study until they go down in dose.

DR. ROBERTS: And from that.

DR. GORDON: And from that I --

DR. ROBERTS: How does that effect your response to this question?

DR. GORDON: I would probably not -- I would not accept this study to base the chromium on. And I'd ask Dr. Shi who knows this field far better than I: Aren't there tons of other studies on chromium out there?

DR. ROBERTS: On hexavalent chromium?

DR. GORDON: Yeah.

DR. ROBERTS: By the oral route?

DR. SHI: Most of the studies are before 1980. Because at that time -- and there's a general agreement that by oral route and chromium is not that bad. And most of the studies focused on the inhalation.

For me to respond to your question, and as I said earlier, the maximum to use is a 5 milligram and the chromium acid is not very strong acid. It's a very, very weak acid. And the stomach can easily buffer that. That's the first.

Secondly, is the use of the chromium VI only, all chromium

VI. Is the chromium VI much more toxic than chromium III? We already talk about it.

And in the playground, just assume we use 100-percent chromium VI. So we already consider the safety margin. So I think that the number 0.5 is okay. You already take a consideration about as primary use the chromium VI. So I think that number is okay.

DR. ROBERTS: Dr. Morry.

DR. MORRY: We did a risk assessment for chromium by the oral route for drinking water in California a few years back. And for the noncarcinogenic effects, as I recall, we relied on an animal study. I think it was a dog study that showed essentially no effects. And so we were just looking at the highest level that's been, you know, that the animal was exposed to that showed no effects at all.

I think that was McKenzie. I hope I'm not confusing it with a different chemical. And I think the same study is referred to in IRIS for an RFD for hexichrom.

DR. ROBERTS: Can the Agency comment on that study, or why it was or was not used as part of their deliberation?

DR. VU: McKenzie? But the McKenzie is the one that is

used in IRIS. Right. And I wasn't sure whether, Dr. Morry, you said there is another study.

DR. MORRY: That's the one I was referring to.

DR. VU: That's right.

DR. MORRY: Dr. Clewell just reminded me that that's a very long-term study, and we're talking here about shorter-term effects.

DR. VU: I mean, the Agency has a chronic reference dose which is relied on the McKenzie study which is also included in the discussion here. And the reason why the Office of Pesticide Program is picking the -- is proposing to use the Tile or Till study is because of a shorter-term duration exposure. That's all.

DR. ROBERTS: All right. Let me see if I can capture a sense of where we are right now. I think we have some members of the panel that are prepared to endorse or accept what the Agency has done as being reasonable. We have some noting the weaknesses in the data base. And we have some other folks that are concerned about the study upon which this NOAEL is derived. And I want to get -- I want to know whether those folks have something to add beyond expressing reservations about that.

In other words, specifically, would you say, I have

reservations about this study. I think we out to use this other study which would change the NOAEL to or would be based upon the LOAEl. I want to try and be specific here.

Yes. Dr. Ginsberg.

DR. GINSBERG: Well, the other study that was distributed to us today or last night does show a LOAEL of 23.6. And if one chose to divide that by 10, you'd be in the typical NOAEL-to-LOAEL extrapolation; you'd be around .26, a little bit lower. Of course, this is not a good dose-response study. It was just one concentration used. So I wouldn't say to use this in isolation either.

But I guess I just haven't looked at the totality of the data base to sieve out and have confidence that that one endpoint in the Tile study should be the key study especially when there's another triogenecity finding in that dose range that they didn't see.

DR. ROBERTS: Okay. Dr. Lees.

DR. LEES: Actually, your comments just triggered something in my mind. This number right here -- and, again, this is as a nontoxicologist -- is the rabbit value. There has not been any interspecies conversion factor thrown in.

DR. CLEWELL: Right. They proposed a total uncertainty

factor with this number.

DR. ROBERTS: That's correct.

DR. LEES: Okay.

DR. ROBERTS: All right. Well, then, I think maybe our feedback, as I gather, it is that some members of the panel agree with the Agency's decision. Other members were perhaps less comfortable with endorsing it because of their concern for the study used to derive this value.

Do you think that represents our consensus at this point?

DR. GINSBERG: Yes.

DR. ROBERTS: Let's try and do one more before we break for lunch because No. 7, I think, is going to be a big one.

VOICE: How about No. 6?

DR. ROBERTS: Okay. Let's do No. 6. I'm sorry. The Agency will read it to us. Then we'll get started.

DR. MCMAHON: Question No. 6 has to deal with the selection of endpoints for dermal risk assessment for inorganic chromium. And the question reads: "To please comment on whether the significant nonsystemic dermal effects from dermal exposure to inorganic chromium should form the basis of dermal residential risk assessments, and if so, how the Agency should

establish a dermal endpoint for such an assessment."

DR. ROBERTS: Dr. Morry, I think you were going to lead off the discussion.

DR. MORRY: Okay. David Morry, California EPA.

This is a question about how to deal with risk assessment for noncarcinogenic effects of chromium, hexavalent chromium, by dermal exposure. And there's really two parts to it.

The first part is: If you based the risk assessment on direct skin effects, irritation, and also sensitization and allergic effects, would that be sufficiently protective that you would not need to concern yourself with the contribution that dermal exposure would make to the systemic effects.

And then the second part of the question is: If you do decide yes to that first question, then how you would you proceed to do a risk assessment based on direct dermal effects.

Okay. As far as the first question is of whether that would be adequately protective to just consider the direct dermal effects, this is usually dealt with pretty summarily by most people who have to face this question, say, well, very little is actually absorbed through the skin and that would only make a minor contribution to systemic effects. So the direct dermal effects are

the endpoint, most sensitive endpoint, for dermal exposure to metals and in this case to chromium.

And I think that's probably a safe thing to do, and you won't be criticized very much for doing that. I don't know if that prediction will hold, but --

DR. CLEWELL: In this group that might not be true.

DR. MORRY: That might not hold in this group.

In the general risk assessment community, that's usually done. If you wanted to go a step farther, what you'd have to do is get actual data on how much of the chromium penetrates through the skin and into the circulation.

Yesterday I heard a figure of 1.3 percent from one of the U.S. EPA presenters. And I looked quickly through what I can find in the literature, and most of the figures I saw were in the range for the percent that would actually enter the bloodstream by the dermal route. Of course, this would be affected by all the factors we've been talking about today and by things like whether the skin is abraded and so forth. We're probably talking about low percentages.

If you wanted to be really thorough, you could take that kind of data and then do a PBPK model and say, okay, now what would

be the contribution from dermal absorption to the level that would be reaching the kidney or whatever, probably would be the kidney, would be the target organ that you would be concerned about and that would address that question.

But I think it's safe to guess that probably what you're concerned about for the endpoint is the direct dermal effects.

Okay. The second part of the question is, then, how would you do a risk assessment based on those direct dermal effects. This is very difficult to approach, and there's not very much to go on. It is clear that chromium, both hexavalent chromium and trivalent chromium, are sensitizing agents; and hexavalent chromium is also very irritating. I guess they both can be irritating, but hexavalent chromium is more irritating.

There is human data, but it usually -- the two source of human data are that it used to be used as a medicinal salve, hexavalent chromium, and then it would cause skin irritation. But that's only anecdotal, and we don't know how much the dose is.

There are some -- I looked at the ASTDR document, and there were some animal experiments where they had some data that would show you how much was applied and what the effects were as far as sensitization was concerned. But I'm not sure. I've never

done risk assessment based on sensitization, so I don't know exactly how you would use those experiments to actually quantitate a dose response on this issue.

And I, also, think -- I haven't had a chance to do a thorough literature search to see whether there is better data than what's available on the ATSDR summaries that would enable you to do a risk assessment based on skin irritation or sensitization. But I think when you're dealing with dermal effects, those are the endpoints that should be the endpoints of concern.

DR. ROBERTS: Thank you. Dr. Lees.

DR. LEES: I'd just like to add one point to that, and this is maybe confirmation here. And that is in the case of the New Jersey situation in Hudson County. The New Jersey Department of Environment or Department of Health after many, many years of studying this has essentially come down upon the dermal, the nonsystemic dermal effects, as being the controlling variable, if you will, in their risk assessment. That's reality. Or somebody else's reality.

DR. ROBERTS: Thank you. Dr. Styblo. Oops, wrong one. Dr. Wargo.

DR. WARGO: This is well beyond my area of my expertise,

so I'll defer to the rest of you.

DR. ROBERTS: Okay. Dr. Shi.

DR. SHI: I just make a comment as they may be closer to the detail to this topic. So far EPA and this panel when we talk about the toxicity and carcinogenicity, we mention more about them separate. And we talk about only arsenate, and then we talk about chromium. We do not put the two together.

And in the dermal, use a dermal -- our study show, for example, chromium VI is a very good cancer initiator; but arsenate is a very good cancer initiator and also a cancer promoter, tumor promoter. So if it was arsenate and chromium together that may make a big difference, one plus one equal 4, not 2. So those are toxigenicity effects, and we never consider that in this panel. And especially for the skin, skin cell, where you study transformation. And, also, urea (ph) also a tumor promoter. And it can enhances that effect that.

I just wanted to make that comment. It may not be related to what we're talking about here.

DR. ROBERTS: All right. Thank you. Dr. Lees, you had mentioned that the State of New Jersey, for their risk assessment, have considered this to be essentially the relevant endpoint to

exposure to chromium. Can you discuss or describe for us briefly how they go about doing that because of the questions is, you know, how should a dermal endpoint be established.

DR. LEES: I wish I could, but really I can't --

DR. ROBERTS: Fair enough.

DR. LEES: -- say a whole lot more.

DR. ROBERTS: So it may be sufficient to the Panel to recommend that the Agency look at the way New Jersey -- Dr. Freeman, can you?

DR. FREEMAN: Basically, what they did is they had physicians look at the skin of the people who they thought were exposed and other people and looked for any signs of skin irritation, dermatitis, erosion, whatever. And they did this for hands, arm, nasal septum, and I can't remember what other body parts.

DR. ROBERTS: And they were able to establish a no-effect level from that.

DR. FREEMAN: I don't think so. Mike Godschfelt (ph) is in the process of doing a long-term study on people who have been exposed. And I'm not sure where he is on that.

DR. ROBERTS: Dr. Morry.

DR. MORRY: Dave Morry, California.

I'll just make the quick remark that I think the big problem is not so much establishing what the endpoint is but establishing what's the NOAEL or LOAEL and how do you do dose. Because as someone was saying yesterday, this isn't in the stomach or whatever; it's on your skin. And all the reports we have are from this medicinal salve or from people who have contacted it occupationally. So how do you determine what their dose is? I think that's the big problem. And I don't know if we can answer that. I can't.

DR. ROBERTS: Okay. Dr. Kosnett. While he's getting the microphone, it seems as though the Panel is endorsing the idea that the dermal endpoint is the best way, most appropriate for dermal exposure to chromium; but we're not able at this point to tell them how do that. Is that fair summarization of where we are?

DR. LEES: And perhaps those in New Jersey might be able to inform us a little more.

DR. ROBERTS: And they might consider taking a look at that. I'm sorry we're not being more helpful, but let me -- Dr. Kosnett, maybe he has the solution.

DR. KOSNETT: I have a question but potentially a

suggestion where more information can be found. And that is from the experience in the industry of the people manufacturing these wood products.

There's one thing cited in the guidance document by Dr. McMahon and Dr. Chen. They cite a study which -- actually, the reference doesn't appear in the back of the document. But it's referred to a study by Borroughs, 1983, concerning contact dermatitis and sensitization in the wood preserving industry.

DR. ROBERTS: Do we know enough about that to know where there is any dosimetry involved in that study?

DR. KOSNETT: I was wondering. Can you summarize that study?

DR. ROBERTS: He's looking at you, Dr. Chen.

DR. CHEN: Basically, it's a paper that discuss the irritation causing chromium skin sensitivity issues in general. You have all different kinds of case reports. But no really kind of endpoint selected.

DR. KOSNETT: Most industries would have some information on worker's compensation claims. Sensitization dermatitis from chromium compounds can be significant once you become sensitized and might readily come to medical attention.

And, perhaps, an area to find out to investigate is the extent to which those have been reported in that work force.

DR. ROBERTS: It may be interesting data, but my only question in my mind would be whether or not there is going to be any dosimetry associated with that that you could use.

Okay. Dr. Ginsberg.

DR. GINSBERG: My recollection of how this area has been attacked by the folks in New Jersey and, also, there's another research group, I believe, Dennis Pastenback (ph) at McClaren Hart, Brett Finley, they've published a few things on this. And I think that they've used extracts of soil and done some bioassay work with that to look at animal model hypersensitivity with the chromium that's extractable.

And as I recall, it's fairly soil specific so we're going to run into that issue in terms of applicability of playground environment versus what soils have been tested in what ways.

And what has not been addressed at all, and I guess that's the reason I decided to grab the microphone, is the issue of anything that resembles a dislodgeable residues, you know, the availability, the urgency, the hypersensitivity potential of that. I don't think we have anything.

As a matter of fact, in Connecticut, we have a soil cleanup standard of 100 ppm based upon this dermal endpoint which we basically stole from New Jersey. Their number may be 50 or 100. It's in that range. But that's ppms in soil.

You know, we're talking about dislodgeable residues in terms of micrograms per hundred centimeters squared. And I don't know how you're going to relate that back to a ppm concentration in soil that is or is not demonstrated to produce from an extract environment. So that's going to be a challenge to come up with the protocol for dislodgeable residue.

DR. ROBERTS: Dr. Clewell

DR. CLEWELL: I mentioned yesterday that there's been a number of epidemiological studies done on workers with CCA wood. I think, actually, it's a fairly rich data base. And these kind of skin conditions are the kinds of things the workers complain of and are noted in the reports. And no skin effects are noted in any of the exposures, including ones where there's substantial urinary arsenic showing that there has been significant exposure.

So it looks like we actually have a better data base regarding the sensitization associated with the wood residues than we do for the soil. But I think then, going back to New Jersey, we have some

information on soil as well.

DR. ROBERTS: Dr. Morry

DR. MORRY: Dave Morry, California.

I'd like to just tell you what Dr. Clewell just said, and he can correct me if I'm wrong.

But you said no skin effects were reported.

DR. CLEWELL: No.

DR. MORRY: Or you meant no systemic effects.

DR. CLEWELL: No skin effects, too. They didn't report any -- well, these are summaries. You'd have to go back and look at the original reports. But, you know, typically these kinds of things, skin conditions, are reported, you know, by the workers when they ask them do you have any health effects from these things.

So the fact that there isn't, actually, is pretty striking. For someone working with chromium, I would have expected to see some records. This would need to be verified by looking at the original studies and evaluating whether that was looked for.

DR. ROBERTS: So Dr. Vu, the answers are "yes" and "we don't know."

DR. VU: Thank you. I think that's fine. The Agency's

always struggling when we deal with respiratory sensitization as well as dermal sensitization. We have tests to look at yes, no; but we really don't know how to deal with dose response and come up with a dose that can elicit these kinds of effects; and that's always been.

So were looking for whether you have any recommended kind of research or testing, whatever; but we understand the dilemma we have. Thank you.

DR. ROBERTS: And there were some documents and possibilities mentioned during this meeting. And to the extent that we can track those down, we'll make note of those in our report. And they may be leads that would be useful for follow-up.

Let's go ahead and take a break for lunch. We have an announcement first.

MS. ODIOTT: We have a series of copies of the different studies that were provided for you. We have them at our meeting room back there. So if you haven't gone through them, please go do that during the lunch break. Because after that, we're going to make the rest of the copies available to the public.

DR. ROBERTS: We may be solving the problem. There won't be any wood left to pressure treat; it will all be directed to

the pulp industry to make copies for the Panel.

Let's take a break for one hour. Please be prompt in reconvening. We still have many questions to cover.

(Lunch recess.)

DR. ROBERTS: I believe we're on Question 7. Could the Agency, please, pose that to the Panel.

MS. VOICE: Good afternoon, Mr. Chairman, and members of the panel.

Questions 7 and 8 as you know are related. Question 7 specifically deals with whether the Agency is conducting a deterministic approach. And question reads as follows:

"Please comment on whether OPP's choice of central tendency and high-end values for different parameters should collectively produce estimates of middle and high-end potential exposures. If the Panel thinks that the OPP approach may not estimate the high ends of the exposure range because it produces values that are either higher or lower than the upper end of the exposure range, please comment on what specific values should be modified to produce estimates of the high end of the potential exposure."

DR. ROBERTS: This is a big question. And I think that

there's a lot of facts and there are lots of assumptions in here. I can really envision this spiraling out of control if the panel members don't exercise some discipline in their responses.

I'm going to go ahead and ask for the input from the lead discussants. But I really want everyone on the panel to sort of work together to come up with our input on this as efficiently as possible. I believe the lead discussant on this one is Dr. Freeman. Why don't you go ahead and start.

DR. FREEMAN: In reviewing the exposure parameters that were listed, they're characterized in three types: General variables, scenario-specific variables for dermal contact with soil, oral ingestion of residues, and oral ingestion of soil residues. And I would suggest that the scenario-specific variables for dermal contact in soil, which is the soil adherence factor, not be discussed until Question 10, since that question deals with that.

What I'd like to go over initially are what are characterized as general variables. Which, for those of you who don't have it in front of, that's age of child, body weight, surface areas, high end being arms, hands, and legs; central tendency being three fingers; and then playground activities, hours per day, one hour; days per year, 130 for the central tendency; and years per lifetime, 6 out of

75.

Amongst these I only have concerns about two. One's not really a concern. The 20-square centimeter for three fingers is adequate for a three-year-old. And this actually sort of hedges off into the next question.

If you're working with two-year-olds, that would be approximately 35 percent of the hand as opposed to what for a two-year-old it really is, which is about 30 percent. The finger to palm ratio changes with the child's age. And it might be better if you had some sort of moving target for your probabilistic measurements. You know, as a rough estimate for the three-year old, it's fine.

The playground activity in terms of hours per day as a central tendency measure, you have one hour. I went back and looked at the NHAPS data, national human activity patten data, and also the data from Silvers, Florence, Rork, et al. And, of course, the problem with all these data sets is they break up the kids in different age groups than what you're interested in.

One of the things that we seem to be saying about this playground equipment is that there's typically not grass around it, that there are other types of media. From the Silvers, et al., group,

what they were finding is that somewhere between 35 and 45 minutes of the day when children are out playing it's on grassy surfaces. So that you may be overestimating the actual contact time with play equipment or with the types of substrates that you assume to potentially have contamination.

Those are the things I have to say on those general variables and maybe other people can talk.

DR. ROBERTS: Okay. And just as, also, some advice or instruction to the Panel. I think as you express opinions on some of these exposure issues, I think it would be important for the Agency to distinguish between things that can be addressed immediately versus things that maybe could be done better that will take some time.

The Agency is under some time constraints in terms of producing an analysis. And there may be some things where it would be really advisable to get some data and improve it. I'm sure we can probably come up with lots of those. So if there's some short-term fixes, things that you just think, based on the data that are available right now, a different value should be picked, please distinguish that between things for which the Agency could collect data perhaps and improve it in the future and refine their

analysis.

Dr. Heeringa.

DR. HEERINGA: Steve Heeringa, University of Michigan.

My response to this question is very much a statistical one. I was quite literal at least in interpreting it as a statistician might. And first of all, I think, as we get into Question 8, an issue will arise as to whether we turn to more probabilistic measures of assessment and to what value can deterministic methods that I used fix constant values for certain parameters really prove useful.

I think we need to step back. And the models for the study of children's acute and chronic CCA-metals exposures, either the ADD or the LAD from play structures. And I emphasize play structures. And you know, it involved this composition estimator through multiplication and division of a number of parameters, essentially derived stochastic variable or multiple sources of state sources of concentrations and transfers and also transitions in the dermal or oral exposure routes.

And I think Doreen Aviado's presentation yesterday actually laid out in a simple proposed formula for several of these exposure estimators. And they really just are products of variables and ratios of variables.

Few things about the endpoint, though, which is this exposure distribution that we'd like to look at and its central tendencies and its quantiles, its 90th percentile. I expect that this distribution will be left-sensored. Rarely at zero exposure but potentially at other exposures related to -- not related to playground or play structure use.

And so I think this whole issue of left-sensoring has to come in in terms of thinking about estimation.

Estimates of the average daily dose and the LAD and their means, the median quantiles should reflect the distributional parameters. This is my view. Means and variabilities of each of the exposure components. So, clearly, one of the recommendations I'll make eventually is to move towards probabilistic and simulation-based exposure assessments.

It also needs to reflect to the extent we know it, and we're not going to have much information, the covarients of the exposure components. And also through sensitivity analysis, the uncertainty, both variance and potential bias, as of the values that we're using as input. And by uncertainty, I mean not so much the variability of those in the natural distributions, if those distributions were known, but the uncertainty about our knowledge

of those distributions.

In addition, we have to understand the influence of covariates like region and climate and many other factors that are not explicitly included in the estimation model. And we've heard a number of people cite specific cases particularly in the Southeast where the exposure and exposure times can vary greatly from those that I see in Michigan, Wisconsin, and other types of places.

But just to get at the simple question of what does deterministic analysis get us here. The question is -- the proposed estimators of the ADD and LAD are the simple product of ratio statistics. And let's look at the central tendency. I assume we can have two measures of central tendency.

The first is the mean value, and the second might be a median value or some quantile close to the median value. The simple answer to the question is, by simply multiplying means or deterministic values that are means of distributions, do we get the mean of the composite distribution. The answer is no; we get some value that is less than the composite distribution. And that's generally by -- excuse me. We get some value that is greater than the composite distribution -- less than the composite distribution by some factor that's equal to the covarients of two the factors that

are being multiplied.

It's a simple statistical, mathematical derivation result. You only have to look at the formula for the covariance of XY to see that the expected value of X and Y is equal to the expected value of X times the expected value of Y plus the covariance. That's a fairly simple expectation that commonly used in statistics.

There's another aspect to this, too, that I think drives us away from deterministic analysis in that in no case do we have estimates of the central tendencies that are measured without error. There are sample estimates or observational estimates. Even if they were pure, proper sample estimates without uncertainty of the general measurement nature, the variability of these products is also going to include an additive covariance term. And I'll have the formulas in here for you to look at.

But that means that, in fact, the variability of the product of these mean tendencies or central tendencies for these two distributions is actually going to be much more variable than what we might expect just by taking the product of the two expectations.

Again, I think the straight answer to that first question is that we can't simply just composite through products expected values and expect that distribution to look like the expected value

of the product distribution.

What about other measures of central tendency or extremes, and namely quantiles? And here we switch to medians. Distributional theory and statistics is more complex here involving dirutial (ph) A type distributions for order statistics.

Again, without getting off the track, I think Peter's graduate students may be able to better handle these than us. I filed those away in my memory about 25 years ago and haven't dug them out.

What I did, instead of trying to work with analysis of dirutial A distributions, I just constructed a simple example. And that is if you would write down -- and this will be in here. If you write down two vectors of variables, an X and a Y; and these are distributions of parameters. X has values 1, 2, 3. Y has values 2, 8, and 14. The median of X is 2; the medial of Y is 8. If you take their product you'll find that the median of the product of X and Y is 16; but the median of XY is 14. So, obviously, the answer is there that even medians do you propagate under multiplication.

Likewise, the same would hold for other quantiles of the distribution. So what is the direction of the bias when we're looking at quantiles of the distribution? It really determines, it's based on the correlation between X and Y. I'm just dealing with

two variables here. If you've got five variables, it just propagates until multiple dimensions.

But even with two variables, that bias is a function not only of the correlation between X and Y but also the distributional shape of X and Y.

So in summary, I've been long-winded here. But the answer is that you can make really no assumption about the biasness of a treating products of deterministic values as essentially those statistics translating over into a comparable distribution where you took the parameters of the actual distribution of the products themselves. So I think that's a fairly straightforward answer.

Now, the question is: How serious are these biases, and does it essentially eliminate the possibility of using deterministic analysis? I think that the biases could be potentially quite serious. And the direction of the bias would be an anti-conservative one at this point.

So I am going to lean more in my recommendations to the use of stochastic measures. And I think, also, if we look at alternatives -- it's part of Question 7 -- that the potential use of some the Bayesian methods where, if we have a potential observed range of parameter values for these distributions, we could assume

flat priors in a Bayesian context over those range and actually incorporate that into our simulations or our probabilistic assessment. Thank you.

DR. ROBERTS: Thank you. Dr. McDonald.

DR. MCDONALD: Yeah, well, if we could answer this question, we'd have all the answers to the risks questions already and we wouldn't need the model at all. But I'll make some observations.

This is a very simplistic model. But as with all simplistic models, there's no harm in trying it and trying a variety of inputs as a first step in understanding exposure and risk.

But I think this implies there's no point in trying to agree on a correct set of inputs at this time, rather these models should be tried with a variety of inputs just to see what you get.

I did note all of the coefficients and parameters seem to be conservatively biased towards overestimating exposure. When inflated, central tendency values are put into the deterministic exposure calculation, that it can be expected to overestimate the expected or central tendency exposure as Steve's already explained.

Another aspect if the distribution of exposure is highly

positively skewed, which I expect it is, this bias may be considerable. Working with the high-end values will be even worse as the result would correspond to the very rare event of an exposure that is extreme in every aspect and, hence, will be higher than is ever observed in reality.

So these issues are best resolved with the probabilistic, and that's to be discussed in Question 8.

I've never tried working off a screen before. Paper is so much better.

For now the deterministic model is to be used, any parameters that are unnecessarily inflated should be reduced. This is best left to those closer to the studies that gave the values. But I would look first at the calculation of skin surface area, replace it by the effective skin surface area. I would look at the hours per day of playground activity. The days per year will probably vary regionally. And I, also, note that the soil adherence factor seems high, but that will be discussed in Question 10.

DR. ROBERTS: Is that it? Thank you, Dr. McDonald. In a sense, we've had at least two suggestions that perhaps the probabilistic analysis is the way to go. And if we ultimately determine that in the next question, then a lot of the debate about

specific exposure factors going through this might become moot.

However, at the same time, you've asked us. And I suppose I'll just preface the discussion that will now follow is that if the Agency were to do a deterministic assessment, what would you recommend in terms of values and holding open the possibility that half an hour from now we may tell you that that's not a good thing to do.

In order to approach this, I'm sure that everyone on the panel has probably taken a look at these exposure assumptions and may have different opinions about which ones may seem, in their impression, too high or too low or do not represent what they're intended to represent.

And I don't know that we're going to have a lot of time for extended debate on that. So what I will do is I will just ask for input from individual panel members. But, again, I don't know that we're going to duke it out on each individual one. Perhaps as the comments come in, there will begin to be sort of a consensus. One thing may get mentioned over another, and perhaps we can come up with a recommendation on that.

But I would rather we didn't have protracted debate on individuals exposure assumptions; again, particularly since it may

become moot when we talk about probabilistic risk assessment.

Let me, then, open this question to other members of the Panel. Dr. Wargo and then Dr. Adgate.

DR. WARGO: If you look ahead to Question 12, we were asked for Question 12 how the Agency might best combine different exposure scenarios. And, basically, I just at this point want to say that I support the suggestions that were made. And they are very consistent with the suggestions that we will make, or at least that I will make, when we get to Question 12. We, too, are moving to recommend a probabilistic approach that would aggregate exposure across diverse sources.

DR. ROBERTS: Okay. Great. Dr. Adgate.

DR. ADGATE: Besides saying amen, I guess one of the things I found bothersome as I read the EAP document, and this is sort of a generic criticism in that, when you look at a lot of these things, what you present is you present what you call a mean and a min and a max, but there is never any idea of what the shape of the distribution is which is really the information that you need.

Now, maybe you didn't have that. I understand that. But I think when you present data, however you present, you should always keep that in mind.

DR. ROBERTS: Dr. Solo-Gabriele.

DR. SOLO-GABRIELE: I agree that a probabilistic approach would be best. However, I don't think we need to do away with the deterministic approach. I think that there's a value to that as well. I don't think one run or two runs of the deterministic model would be adequate. You can run it using a whole series of different assumptions.

The assumptions that concern me the most are the ones that are more affected by regional basis, for example, the exposure time and duration. It would be useful to run the deterministic model maybe for different regions of the U.S. Maybe one for the region of the south versus the north and see how those compare.

DR. ROBERTS: Dr. Clewell.

DR. CLEWELL: I agree regarding the fact that there may be some value to looking at a deterministic evaluation and then going on to a probabilistic. And if that's done, the main parameter that bothers me is the hand-to-mouth frequently which I think there was some presentation to the panel on the fact that there are empirical measures that suggest that the behavioral estimates are high-sided. And so I wouldn't call the value that EPA's using a central estimate. I believe it's actually a fairly high value.

DR. ROBERTS: I think Dr. Freeman would like to respond to that. And then we'll get to Dr. Ginsberg.

DR. FREEMAN: The presentation that discussed that was using the data of Zartarian which were four children. There are larger studies now that have gone and evaluated and to some extent it becomes age-dependent. While for a four-year-old, the number they gave in terms of actual in-the-mouth surface contacts may be right.

There is another behavior that you see with the younger children. And that is the kid licks the whole hand. The hand never goes in the mouth. But the licking -- you don't see that in a four-year-old. You see that in a two-year-old and a one-year-old.

And since this is supposed to cover the whole range, what I've done in some of my more recent calculations is I've gone with the median of that 9.5 which actually is 8.5. It's just a modest reduction, but it tries to take into account. You know, it's not a perfect data set for all children.

DR. ROBERTS: So would you recommend that perhaps they need to take a more focused view on specific age groups?

DR. FREEMAN: Yes.

DR. ROBERTS: The one to six is just too big an age range

behaviorally --

DR. FREEMAN: Yes.

DR. ROBERTS: -- to come up with exposure assumptions.

DR. FREEMAN: That also holds for time on playgrounds. With the one- to three-year-olds, the child typically has to be taken to the playground by a caretaker. When you're talking about four-, five-, and six-year-olds, there may be a level of independence whether it's in a day care program or the swing sets in the back yard. And so the amount of time you're actually spending out there for the little kids is driven by the caretakers needs as much as the child's needs.

DR. ROBERTS: Thank you. Dr. Ginsberg.

DR. BATES: Michael Bates. I'm also leaning towards a probabilistic mode.

DR. ROBERTS: I'm sorry. Dr. Ginsberg, and then you'll be up next. I'm sorry.

DR. GINSBERG: Again, the bigger picture, what we're trying to accomplish here with this risk assessment, EPA has said to us that they're shooting for what the central tendency estimates, a realistic assessment. And I assume that that's to understand whether some division in the registration process or something

that effects the registration of this material. You know, if we can develop a realistic set of risk estimates, then you can make a clear judgment about the safety, the ongoing practice.

But what -- I mean I think as we're hearing from other presenters so far is that any attempt at that is going to have a fair bit of uncertainty and what we really need to do is look at the full range of possible values. And what we're used to more doing in risk assessment is developing exposure estimates that we try to make sure don't underestimate what's possible.

So that when we make -- so then when the risk managers make regulatory decisions, number one, they need to understand all the uncertainties and it needs to be transparent what those assumptions are. But that they know that they're being at a level that will protect public health.

What I'd feel more comfortable with at this stage knowing that we're just doing -- and the whole process and field data and that an interim step here and the whole process means you're going to go out and get more field data. And there may be better opportunities to develop distributions, as has been said here already, is to define parameter estimates that are going to be protective of, say, you know, the South, you know.

If you need to develop one estimate that's going to sort of in a decision-tree context or, you know, a number of years of exposure that we know are protective. And through these exposure assumptions, we see that the risks are elevated then you could -- or elevated to the point where, gee, you know, we really need to refined it more. Then you go into the refined probabilistic analysis.

So there's a number of things in here that I wouldn't have picked numbers. You know, I can easily envision scenarios where 130 days, even in Connecticut, would not be appropriate when we're talking about both playground and backyard. And you know, I could see seven hours a day for some kids. It's not going to be the central estimate.

But there will be children that could be exposed to more than that central estimate, which you have the high end, I know. But that high end is only for cancer and -- I'm sorry -- the high end is only for acute, rather. So it's a different assumption.

So there's a number of -- I'm not going to go through my list of changes that I'd suggest. But I could certainly envision higher estimates to do the screening level. You know, do we think there's something going on or potentially needs to be refined in certain

pathways.

Regarding the discussion about dislodgeable and, you know, how much hand-transfer and the empirical, I think Harvey was trying to talk about the empirical versus the behavioral. I had done some calculations, actually, spurred on by some of the presenters on Tuesday, about what -- how -- is the amount of soil that a kid could be ingesting with this 9.5 events per hour, one or three hours a day, you know, how much dust, dislodgeable residue, is actually being ingested. And we didn't really on have -- on Tuesday, anyway, nobody really presented an amount on the hands, you know, that was realistic, I felt, to a surface-coating exposure from a deck.

We were talking about soil loading from playing in dirt. But what has come to mind for me is that and, also discussing this with Dr. Freeman, the concentration on the deck in terms of dislodgeable dust is probably on the order of .05 milligrams of dust per centimeter squared. And there's a couple of ways to get to that number. And I could go through that with you. I don't want to take the time now.

But that seems to be a good number. And if you assume a one-to-one hand transfer efficiency, now we've got .05 milligrams

of dirt per centimeter squared of hand. When you use that number and plug and chug through the 9.5 events per hour, one hour a day, 50 percent transfer efficiency, the calculation for dust dislodgeable dirt ingestion is -- oh, what was it? -- is 4.8 milligrams for the average case and up to 30 milligrams of dust for the high-end case of dislodgeable dust ingestion.

So I actually think that those numbers seem fairly reasonable, especially when considering that the amount of dust that a child could ingest from being indoors and, you know, the hand picking up dust, we're assuming that that could be up to half of what the child could get from the whole day of exposure and so talking on the order of 50 milligrams per day from indoor dust ingestion. And the amount of dustiness, it looks very much now, that the amount of dustiness on a deck could be similar to the amount of dustiness in an indoor house environment.

So I endorse, actually, the central tendency and the upward bound for the hand-to-mouth, hand loads per day, you know, that kind of estimate.

DR. ROBERTS: Thank you. Before we get to Dr. Bates's comment, I just wanted to ask the Agency a question because it may help clarify some of our discussion. It was prompted by

something that Dr. Ginsberg brought up.

And that is it's not clear to me. Is this how this risk assessment is to be used? Is this, in a sense, sort of like a screening-level assessment even though it involves central and high-end exposures such that perhaps a decision would be made whether or not this situation poses a problem?

And if the answer to that, according to this analysis, is yes, then the Department would go back and say we really need to take a closer look at this and we need to do a more refined assessment. Or is this, you know, we're going to do this once; we're going to do the best job we can; and that's it. And depending upon the approach, I think it probably depends on how concerned we are about the conservatism or really how we approach some of these exposure assumptions. And could I ask for a clarification from the Agency on that?

MR. COOK: Basically, I spent 20 years on the ag side. Somehow I ended up on this side. We did environmental risk assessments. But, basically, from my experience, and this seems to be true on the human side, you're correct. To me these are basically what you would call hazard quotients or risk quotients, and we kind of loosely call them risk assessments.

They're quick and dirty. For a regulatory agency, they're great when they show no risk. They work wonderfully then.

The problem is when you get toxic materials like arsenic, low levels, variable data, they don't work very well. So I think the Agency is moving into a tiering, like Dr. Ginsberg said, where the first tier might be the screen. And then you'd move into a probabilistic because I know they've done that on the environmental side. I've built two or three in that.

DR. ROBERTS: Okay. And what we're seeing now would be, in essence, the screening level assessment; is that correct? Dr. Edwards, I think, wants to clarify.

DR. EDWARDS: Well, I think in Question 7 you're saying probably, and we may have not communicated this as well as we might have. But that would be more of a screening level assessment. When we move into Question 8, that's probably more of trying to get a realistic assessment.

And what we intend to produce when we do a risk assessment is the most realistic one we can. And I think what might end up happening is if, in fact, you found no problems with the screening level, you wouldn't need to expend the extra resources and do a probabilistic, which is much more sophisticated.

But we would like comment from the Panel on if we did move to probabilistic, what would make the most sense to do; and, also, whether it even makes sense to do a deterministic as a screening level. Does that help?

DR. ROBERTS: No, it helps a lot because I think it's important for the context of looking at these values. In a screening level assessment, of course, you want to be sure and capture the high end because you don't want to decide there's not a problem if there is.

No. This helps enormously, I think, for the Panel to sort of put into context the issue of a deterministic analysis versus a probabilistic analysis and how they would be used in the decision-making process.

DR. WARGO: May I respond to that?

DR. ROBERTS: Dr. Wargo will respond to that point very quickly. We need to get back to Dr. Bates and Dr. Smith.

DR. WARGO: I think that the deterministic approach can give you false comfort under certain circumstances, especially if you have heavily skewed distributions of behavior of contamination. And that is often the case.

And by this, I mean, if you have many zeros in your data set

and you have a couple of high-end values, say, 9 percent of your values in your data set are very high end, then even your 90th percentile value is going to be zero. So in doing your rough-cut deterministic approach, the median, the 90th percentile, will return a zero value. And you may walk away saying there's no problem, when the reality is you've got 9 percent of the population that could be heavily exposed. That was one point.

The second point is that on the modeling issue, it's easy to do now. And the Agency has already made great progress in the pesticide division in the food safety area under FQPA. And that logic, that approach to modeling, is directly transferable to this scenario. And you've got people that understand it and you can move forward quickly.

In response to your question, Steve, I like to think of this as helping them to frame out a model that will really be kind of a living model that will change over time as they get that greater understanding about the various factors or parameters that they're putting into it as they have clearer understanding of what those distributions are.

DR. ROBERTS: Thank you. Dr. Bates has waited patiently. Let's let him make his comments, then Dr. Smith and Dr. Clewell.

DR. BATES: Well, like many colleagues here, I support the use of probabilistic assessments even if deterministic assessments are also used as screening method.

I have some concerns about the estimates for oral ingestion of residues as I mentioned yesterday in response to one of the presenters. I believe there's a need for an additional factor in there which is sort of a reloading factor because there is an assumption built in there that between every event there's a reloading of the hand so that the 50 percent can be removed each time.

So I suggest that that wouldn't always happen between hand-to-mouth events and that an additional factor needs to be incorporated and whether it's a deterministic of a probabilistic model.

DR. ROBERTS: I think Dr. Freeman wants to respond to that.

DR. FREEMAN: I think that's a very interesting point. For those of you who aren't aware of some of this behavioral data, what we do when we're quantifying kid's behaviors, which we do with a computer program that allows us to look at frequency and duration of contacts.

The average duration of a contact a child has with a surface is about four seconds. The child has hundreds of these contacts before a mouthing event occurs. Charles Rhodes's laboratory studies suggest that a hand basically maxes out in terms of loading somewhere between four and ten contacts. So that if the child was mouthing outdoors, which I have a concern about because most children other than babies don't do that, that it's always in the state of replenishment at the time the fingers go into the mouth because they're constantly touching things. And after about four or five touches, you know, you've got your maximum loading that you can have.

The Rhodes's work was actually done not with soils but was done with dust particles. So what happens outdoors may be slightly different.

DR. ROBERTS: Dr. Smith.

DR. SMITH: Andy Smith. State of Maine.

I guess, let me start first, by given your response of this sort of tiered approach with screening and possibly being refined to a probabilistic, I would feel much easier responding if Question 7 said something more like provide us your input on the selection of these specific values for use in a screening level analysis.

But that's not what the question says. What the question asks us is do we think that the central tendency values in the high-end values produce estimates in the middle and high-end range. And I agree strong with the statisticians and others on this panel that we have no idea.

I mean, if you don't do it in a stochastic way and try to make some sort of approximation, we don't know what we're ending up with. We don't know what we're ending up with because of different possible shapes of the distributions because of the correlation structure between them. And I'm very concerned about the correlation structure between age and hand-to-mouth behavior as well as a number of other factors.

So I would feel comfortable getting into a dialogue about what values ought we to use and not use in a screening approach if I thought that was really what you were asking us. But I'm having trouble responding because the question as it is is one I don't know how to answer in a deterministic way.

DR. ROBERTS: Well, I can fix that. Basically, our response could be that, for example, the Panel would recommend using a deterministic analysis only for screening purposes. And for that purpose, you know, this is what we think the inputs should

be.

DR. SMITH: Uh-huh. And I think under that scenario, my response, I think, would be there are certainly some parameters that I have questions about. But the way I would prefer to see them approach this is, rather than say let's modify one a little this way or that way, maybe instead of just doing the deterministic analysis as one or two scenarios, maybe make it three or four to try to get some sort of sense to what are the big driving factors and just how variable they are.

So for example, you can imagine under the duration rather than it just being 130 days, you might have several scenarios. One has been described to reflect warmer climates and others.

One particular one that I'd like to you think about is in terms of the six-year scenario. The six-year scenario seems very plausible for me although with a caveat about the interaction between age and hand-to-mouth activity. If we think of our own anecdotal experience, and I have two. I have a three-finger sucker and a thumb sucker at home.

And I have pictures of them on my pressure-treated deck if you'd like that, too. But that really starts to really trail off at six years of age. So for that scenario, I'm completely comfortable

with six years.

But if I start thinking about dermal contact and I watch people on playscapes, well, that goes a lot longer. A lot of schools have playscapes. When you get into Maine and rural towns, there isn't a community playground; there's a school playground. And that's used extensively right up through the entire elementary period, less so as they get older and they're more into sports. But certainly through that period.

So I would encourage you as you're looking at these variables to be thinking of, rather than trying to focus on one, perhaps focus on several different scenarios at this early screening stage.

DR. ROBERTS: Thank you. I think Dr. Vu is going to correct something I just said.

DR. VU: No, not at all. Actually, the Agency is certainly receptive to revise Question 7 to reflect what Dr. Edward is really asking the Panel is, that if the Agency were to do a deterministic approach to do a screening level, what value based on the recommended value, as Dr. Aviado explained earlier in the document, what parameters should we use and which one you would not recommend. And then, of course, recognize you all

recommending the probabilistic approach, which will be Question 8.

DR. ROBERTS: Okay. Thank you. Okay. With that clarification or that understanding, would it be fair to say -- let me throw it out as a proposal -- that the Panel would recommend using a deterministic assessment only for screening purposes? No. Dr. Clewell.

DR. CLEWELL: I share the skepticism of Dr. Wargo regarding the value of a deterministic evaluation for a screening. I don't see why a screening is needed in this case. Screening is useful when you have sites and you're trying to figure out where's the problem and where do I focus my attention.

The attention is focused. People want to know. And they don't really need to hear a bad answer that was done for a screening level and then try to convince them, well, now we've done it better and this is really the answer. What they need to hear, the first number they need to hear, is the one that you actually believe might have some validity.

So I saw the difficulty with the probabilistic risk assessment is mostly a kind of technology gap, that there are people who have never done one, don't know that they trust computers to take away

their judgement. They see you put all these distributions in and out comes a distribution. And they say, I just don't feel like I really...

So if you can use the deterministic risk assessment multiple-valued, multiple runs of a deterministic to help inform people to understand the results of the probabilistic risk assessment and put it in perspective, I believe it's valuable for that. I'm very much against doing any sort of a rough screening for something that is clearly a significant societal impact and should be done right the first time.

DR. ROBERTS: Okay. Good points. Dr. Kosnett.

DR. KOSNETT: I had a question about two of these parameters, and perhaps people from the EPA can help clarify it. One is the issue of years and then lifetime exposure, 6 years out of a 75 lifetime.

Am I correct in that you're interested in that duration or those parameters in particular for calculating cancer risks?

VOICE: If I might clarify. Yes, that goes into the LADD equations for the cancer risk.

DR. KOSNETT: There's just an interesting -- and I don't have a definitive answer for you. But I want to just draw

something to your attention with respect to some emerging information regarding arsenic and cancer risks. And that is traditionally most cancer risks have been based on your average exposure over a lifetime because they've been derived from the experience of reference sets, either animal studies or sometimes environmental studies, where the exposure has occurred over a lifetime. So then the exposure of the people in question would be averaged over a lifetime.

You have a interesting situation with arsenic recently, relatively recently, in Chile in which case there really is a peak period of exposure that occurred in the population there between 1958 and 1970 that was much higher than during other periods of times because that's when an elevated source of water was delivered to Northern Chile, not the entire area but the Antabecosta (ph) area in particular.

DR. ROBERTS: Dr. Kosnett. I hate to interrupt. Is this going to lead --

DR. KOSNETT: Yeah, I'm getting to this point. And essentially the risks that were observed during that 12-year peak are relatively congruent with the risk in Taiwan which are based on lifetime exposures.

The point being is that it's not altogether clear that for the arsenic risk slopes that they necessarily have to be averaged over a lifetime. I don't know the answer to that. I think that's important to bear in mind. And maybe in the future we'll learn additional information. Maybe my colleagues, maybe Dr. Bates or Claudia Hopenhayn-Rich, wanted to comment on that as well. But I'm not making a definitive judgement on it; I'm just pointing that out.

DR. ROBERTS: Actually, I'll comment. I'll concur with your comment. I think there are some data and some analyses out there that support for other carcinogens some difficulties or uncertainties associated with using lifetime average daily dosing. And I can provide those to the Agency. And I think we should. Although, again, it's not in the context of any of these questions. And I think it's probably worth bringing up. Dr. Ginsberg.

DR. GINSBERG: But I think it is directly in the context of the question because their exposure scenario and risk calculation is 6 divided by 75. So if there's anything unusual going on in those first six years of life, for example, a lot of exposure to dislodgeable residues or some other factor, it is going to be diluted out by tenfold in terms of exposure dose.

And if those six years are a unit of risk, a susceptible period,

if those six years can be seen as important of an exposure as a lifetime of exposure later which is the case, now the Agency has recognized with vinyl chloride in terms of the IRIS document which suggests that short-term exposures early in life can be as important as a lifetime of exposure but starting in a sexually mature animal.

And, you know, we have at least one precedent for that. And also cases could be made for tamoxifen and DES on hormonal chemicals and also cases like that, not just for geneocarcinogens. But also there's dieldrin in DDT data that suggest early life exposure can be as important by itself as lifetime exposure starting as an immature animal.

So the 6- to 75-year equation there, if you do use it, I think you have to recognize there is uncertainty and possible underestimations of lifetime cancer risk.

DR. ROBERTS: Okay. We'll raise that issue, and I think we can probably provide some papers to the Agency to support that.

DR. CLEWELL: Can I clarify something on the vinyl chloride? They didn't do an adjustment by a factor of 10. They actually just doubled the adult value. The investigation of vinyl chlorides suggests that that's appropriate. I think that it's in

childhood more important you shouldn't divide. You just may need to be consider this in addition to that. I still support lifetime average daily dose enhanced in the child.

DR. ROBERTS: And I think we can point out some quantitative analyses associated with that uncertainty. Let me -- Okay. Yes. Go ahead.

DR. KOSNETT: I have a second point. And this is a question issue.

I notice you have oral ingestion of soil residues and you have 100 milligrams per day for the central tendency and 400 milligrams per day for the high end. I don't see a factor for the fraction of that soil intake which would be attributed to, for instance, the playground site.

Was that something that was also going to be factored into it, or were you going to do these analyses considering how much of that 100 milligrams a day is going to be attributed to the site if the exposure time is one hour per day or something of that nature?

VOICE: I can start out first. Truly it is an outdoor scenario. The 100 and the 400 do not include any sort of dust from the interior, inside the home. That is specifically recommended values for outdoor settings for total soil ingestion over the day. If

that answers or begins to answer.

DR. KOSNETT: Maybe I'm still not following it. If somebody -- you're assuming that the person's total exposure is 100 milligrams a day. But how much of that are you going to assign to a specific site when you're doing a risk assessment if the assumption is that they spend only an hour at that site a day?

I just didn't see that kind of parameter in here, and I just had a question about that.

DR. DANG: Winston Dang, for the Antimicrobial Division.

This hundred milligrams we cited from 1989 Calabrese study from 400 children. And we adopted the mean value from this and recommended by in exposure for the hand. So in other words, that's 100 milligram that do not have distinction between the playground and also where the other soil contaminator is from, dust or from other area.

DR. KOSNETT: Yeah. So do a risk assessment at a playground. And you're going to say, well, the child is taking in 100 milligrams a day outdoors for the time he's outdoors. How much are you going to assign of 100 milligrams to the playground?

DR. DANG: That's --

DR. CLEWELL: All of it.

DR. KOSNETT: All of it. And you might want to consider whether that's realistic.

DR. DANG: Yeah, that's like a -- we just mentioned we assume is 100 percent but, of course, have some uncertainty analysis may have to incorporate there.

DR. ROBERTS: Dr. Kissel raised his hand. Before I get to him, let me, in an effort to try and move things forward. I have not so far, in any of the comments, heard any enthusiasm, frankly, for doing a deterministic analysis.

Let me follow up, then, on Dr. Clewell's suggestion and throw it out on the table. Would you, Panel, recommend that the Agency should not conduct a deterministic screening level assessment; they should go to a probabilistic assessment?

DR. KOSNETT: I don't know. I don't know.

DR. ROBERTS: Is there agreement on that?

DR. CLEWELL: I would agree with that.

DR. ROBERTS: Dr. Solo-Gabriele.

DR. SOLO-GABRIELE: I still that there's a benefit to running a simple model and getting some data prior to running the more elaborate probabilistic model.

DR. ROBERTS: Okay. Certainly, you could use

deterministic calculations in the process of constructing a probabilistic analysis. But I think what we're sort of talking about is doing an analysis, drawing some conclusions, whatever they are, and deciding whether or not to move onto another tier.

And I guess what I'm asking the Panel, since I haven't heard a lot of support among the Panel for a screening level deterministic analysis as a product from which a decision would be made. Would the Panel think that the first shot out of the block should be a probabilistic assessment in which case we move to Question 8? Or is there value, or is this something which we don't have consensus? Dr. Heeringa.

DR. HEERINGA: I think the consensus that I heard is that, while deterministic analysis does not have sort of long-term ultimate utility for the EPA, that some initial crack at it just to get a feel is certainly warranted. I mean we're always willing to look at numbers and judge their utility.

I think the other suggestion which Dr. Ginsberg raised is to -- you know, there are six parameters in this model. You have a central tendency value and an extreme. So you've got sort of two to the sixth possible models that could be fitted for all possible combination of these parameters, and you could do that in an

Excell spreadsheet in probably about three or four hours.

So I would recommend go ahead and do that, and then essentially you've spanned the range of the 64 models for your deterministic parameters to look at every possible combination that you potentially could have. And that gives you some sense. And I think from there you launch to, I suspect, what is apparently a more threatening exercise or at least a more labor-intensive exercise of developing a proper probabilistic approach.

But I think that would give you a general sense of what the deterministic models and sort of exhaust the possibilities unless we discuss different central tendency and different extreme values. But even if we come up with those, you still have two points to look at. And I think it would be good sense to sort of survey the field then.

DR. ROBERTS: Dr. Kissel had his hand up earlier, and then Dr. McDonald.

DR. KISSEL: The playing field keeps changing every time I think to say something.

I guess I don't even under the concept here of recommending to do a deterministic analysis or not. You've given us numbers. You haven't multiplied them together, but I sat down and

multiplied them together. I suspect people in the audience have sat down and multiplied them together. I suspect that you've sat down and multiplied them together. You just haven't written it down and handed it to us.

So I think probably everybody here knows what happens when you multiply these numbers together. So we're already past that point. And why would we recommend to either do it or not do it at this stage? I think the obvious answer here is you're going to project really big risks if we keep the numbers as they are. And if there's any concern about that, then we have to go and do something else, which I've been pushing for a probabilistic analysis all along.

I also, I guess, kind of object to the notion that you choose between one or two of these things and this is the end of it. I think there is another phase which is the truthing of this process which means you have to go out and do biomonitoring and try to figure out if the numbers make any sense. And just multiplying these things together without that intention, ultimately, is kind of a sterile exercise.

The one other thing that I wanted to say because I was looking up that you wanted to know whether things were high end

or not. There is one piece here that I think could be -- most of these assumptions you're making, I think, are conservative. Although we did boost up the soil availability number a little bit but not greatly.

Something that's not in here is pica. And EPA has traditionally shied away from that because there aren't any really good numbers to deal with it. I think the evidence for soil pica is better then is kind of led on in this document. Some kids do occasionally eat big hunks of dirt.

There is some confusion, by the way, in the document on page 16 in the background document. The exposure scenario which is described as incidental ingestion then has a sentence which says, "Using hands or utensils to pick up and eat CCA-contaminated soil."

That sounds to me like pica and not incidental ingestion. Incidental ingestion is that you lick your finger because you wanted to put your finger in your mouth not because you wanted what was on it to get into your mouth. If you're picking up and eating stuff, you're engaged in pica behavior. So you're describing pica, but you're calling it incidental ingestion.

And the other piece of that that's not conservative is that

while we may have a bad handle on soil pica; we have zero handle on nonsoil pica on just picking up a piece of wood that's CCA treated and eating it. And I think the risk from that might turn out to be very large compared to all this other stuff that we're talking about. And so we really ought to make some attempt to find out to what extent kids actually do that sort of stuff.

MS. AVIADO: Maybe I can just respond if possible to further classify it for you.

Certainly, when we put the background document together, there are certain aspects of the characterization that were not further refined in time for this. That was something I, myself, had looked at and flags went up as to a confusion.

Now, our exposure factors handbook, as you may well know, for the pica child, they look at a range of ingestion that, I believe, it's 10 grams as their recommended value for true pica behavior. And the data from the Calabrese study included an estimate that they attributed to a pica-type behavior in a child, which is why your 400 high-end values seems a little bit higher than anticipated.

But the behavior itself that you're talking about, Dr. Kissel, a three-year-old child may in fact be licking at residue off the hand or engaging in literally eating dirt. But the level of the

ingestion would still be considered nonpica.

DR. ROBERTS: Do want to respond?

DR. KISSEL: I'm not sure who's definition that is. I guess that's yours concocted here.

I think distinction ought to be deliberate versus inadvertent ingestion is pica or not pica and amounts can be quite variable. And the 10-gram standard, that's kind of an old hoary number that's been around for a long time; but it doesn't have too much basis in anything that I'm aware of.

And I think there's more kids out there. The Long work from Jamaica, there's a bunch of kids that are above a thousand milligrams in a given day. You know, you can start running the numbers and try and figure out how much of a surface a kid has to lick and how heavy the hand has to be loaded and that sort of stuff; and it gets to be difficult to deliberately -- to nondeliberately take in that kind of soil.

There's that 480 milligram a day construction worker number out there. And, personally, I've had 20 milligrams of dirt in my mouth. And the immediate reaction that I wanted to have was to spit. So you have to want to be doing that to be ingesting big clumps of dirt at one time. So to get to the thousand milligram a

day and those kind of numbers, I think it has to be deliberate behavior. And so I wouldn't draw the distinction on the basis of some number.

MS. AVIADO: No, that was not my intention. And, if it came across that way, that certainly isn't the Agency's position. I believe our position is to characterize truly the incidental ingestion. But you raised the point of maybe, as a side point, should the Agency consider including behavior for children who do, in fact, eat soil as a pica type.

DR. ROBERTS: I have Dr. McDonald, Dr. Smith, Dr. Kosnett and Dr. Ginsberg. But we need to start coming to closure on this particular question. Dr. McDonald.

DR. MCDONALD: Pass.

DR. ROBERTS: I didn't mean to intimidate you. Dr. Smith.

DR. SMITH: It may hopefully to push us in the direction of closure. I would just like to echo that my complete support for the comments that Dr. Kissel just made, leaving aside the solid ingestion; but in terms of the let's just go straight to a stochastic analysis or probabilistic analysis.

And just to emphasize that we've got already a half a dozen various versions of screening-level risk analysis that have already

been done by various state agencies, by environmental groups, and by industry. So we've seen lots of different permutations of how we can slice and dice this. And we know that we can come up with numbers that suggest that there's very significant exposure, which I also agree, argues for it.

We ought to do some biomonitoring check on that. And that we can get numbers that are very low. And I think that means that we have to do a stochastic analysis to try to get a better handle on this, and we still need to do biomonitoring.

So I would -- then I guess it started with Mr. Clewell that I would agree that at this point I really don't see a value, and I haven't heard a clear sense from the Agency of what the value is going to be for the deterministic analysis if all it's going to do is most likely result in you saying, oh, well, we need to do a more sophisticated analysis.

DR. ROBERTS: Dr. Kosnett can you add to that or move us, also, in the direction of closure?

DR. KOSNETT: I don't have an opinion on that aspect. But I wanted to just say one thing in response to what was said about the pica scenario. And that is you know, that is an issue, for instance, being addressed right now in Region 8 in Denver. It can

have a profound impact on the ultimate decisions about the risks associated with a site as to whether or not you're going to consider whether you want to protect against the possibility of 10 grams. I mean, it can have a huge impact.

And, really, I would agree with Dr. Kissel. We really just don't have good data on how frequent it is and, to what extent, how it occurs. Should we use fine-sieved soil bioavailability when it's done? Usually fine sieving is done because fine sieving is associated with the low level hand-to-mouth contact. It's the dust. But when you're talking scoops of soil in your mouth, maybe we should do crudely sieved soil for bioavailability. And it changes everything.

So the bottom line is I really think that this needs to be studied and funded. And I think ATSDR is actually interested in this very much, too; so maybe you can get to the together with them and help them. I'm sure they would appreciate the funding.

DR. ROBERTS: Okay. I have so far proceed to probabilistic analysis, consider pica, and then there were also some comments about considering lifetime average dosing as -- Dr. Ginsberg

DR. GINSBERG: Yeah. Regarding the potential value of deterministic assessment, I think that there are a number of

different scenarios that can be prioritized for probabilistic. If one does a high-end or screening level deterministic assessment, you may find that there are certainly risk drivers. Maybe you could figure out that the occasional pica behavior is or is not an acute risk or is unlikely to be an acute risk or is likely to be an acute risk. And maybe, then, you could understand the need to really beef up the data and understand the full distribution of that.

Maybe we can understand from some high-end deterministic approaches that dermal is or is not a big factor here or could or might not play a big factor; that the soil ingestion component versus the dislodgeable component, how important they may relatively be. Not a final decision on that, but just where do we want to spend.

Because I think it's easy to say let's do deterministic -- I'm sorry -- probabilistic approaches and show the technology is there to do this on a computer. But my concern is where are we data rich and where are we guessing especially about the tails of the distributions where we're going to be predicting high-end phenomena.

We protect in the 90th percentile child, the 95th percentile child. When you get up in those high-end distributions on any of

these, you have the most uncertainty. And I think we should limit those exercises to where we have the best information.

And we're not going to have great information in every area. Are we going to have great information on dermal? Are we going to have great information on dislodgeable, you know, a penchant for dislodgeable intake? I don't know where we're going to be data rich and where we're not.

But I would think that some prioritization up front through some screening level deterministic may be a good way to get into that.

DR. ROBERTS: I think, Dr. Ginsberg, you launched yourself well into Question 8, which is okay.

Let me, then, propose is it the consensus of the Panel that they should proceed to a probabilistic analysis, and then they should consider pica behavior in some form in that analysis?

DR. KOSNETT: They need to study it.

DR. ROBERTS: Consider it to the extent that they're able. We can make a recommendation that they study it. But, I mean, in the short term what they're going to be able to do, I think, is probably make the best use of what data they can find out there. And then the other point that was raised about average daily

dosing.

Is the Panel in agreement with those points?

DR. KOSNETT: I think just say to study it, the pica behavior. I'm uncomfortable recommending to them that they come up with some parameters and then just apply --

DR. CLEWELL: More research is needed.

DR. KOSNETT: I think it's a legitimate, important thing to do.

DR. ROBERTS: I think from our discussion there was enough concern that that's behavior that should be considered. And I don't know that we're -- "considered" is a pretty open-ended word in terms of how they're able to --

DR. KOSNETT: I don't even think they can make up a number to use. It's just an issue. I don't want to be misinterpreted. I don't want to say that they should add a parameter and come up with values for pica because you just don't know what to put in it.

What I'm saying is this is an issue that communities are asking about. I'm just recommending that you study it.

DR. ROBERTS: Dr. Kissel.

DR. KISSEL: I think I'd be satisfied if I saw a line or a

caveat that said we are aware that there's another issue and we didn't deal with it because we didn't have any quantitative basis for doing so; but not to just ignore it altogether, which is what's been going on for quite a long time.

DR. ROBERTS: And I think that considering doesn't mean that's incorporated into the analysis but at least acknowledged. Dr. Smith, moving on closure.

DR. SMITH: Yes. The only expansion I would make on going straight to stochastic analysis or probabilistic analysis is I would also encourage them to go straight to an aggregate exposure analysis and not just focusing on the playscape.

DR. ROBERTS: Let's talk about that when we talk about number 8.

Dr. Vu, have we --

DR. VU: I think on behalf of the Agency, we appreciate your recommendations. And I think it's a sound one, and we can go ahead with Question 8. And I would suggest to help you, the Panel, for deliberation for Question 8, perhaps you can pull out the EWG overheads that have all these parameters.

And in their analysis, they have certain parameters to be fixed and certain variables, and perhaps we can have some

discussion around those that will be helpful for us when we're going to proceed with the probabilistic risk assessment. Because as you know, some parameters have actual data, you know, there's some uncertainty surrounding different parameters.

DR. ROBERTS: I was hoping we could skate through 8 pretty easily. But if you want input on specific distributions, I think your request is a reasonable one if we can find among the enormous stack of papers that. But that's probably a reasonable way --

DR. CLEWELL: Actually, they're all right here. I haven't turned it in yet, but I already did that.

DR. ROBERTS: Well, in that case, let's go on to Question 8. I think at least part of it has been answered. But there's much, obviously, we need to provide the Agency in terms of feedback for that.

Let's go ahead and read Question 8, if you would.

DR. EDWARDS: In essence, Question 8 deals with probabilistic methods. It says, "Please comment on whether the existing data bases on variability of the different parameters affecting exposure are adequate to support the development of probabilistic estimates of potential exposure. If the Panel regards

the data bases are adequate, please identify which parameters should be addressed using a distribution of values and which data bases should be used to supply the distribution for particular parameters."

DR. ROBERTS: Dr. Clewell, you're primed and ready to go on this one.

DR. CLEWELL: Yes, just point me and fire.

I am glad that Dr. Vu asked you to get out the EWG analysis because I, also, was very impressed with it was an example, just as an example, of one level at which one can do probabilistic analysis. And I thought their presentation was very nice.

As I mentioned under Question 7, I do believe that it must be, this whole thing must be seen as something that will be a major activity that will involve multiple iterations of definition of the parameters and distributions, the approaches, the extent to which things are varied, which parameters are varied.

And, I, personally if I were doing this kind of a project, would do both multiple deterministic estimates to get a general feeling for the kind of range of scenarios and impacts of different aspects and a more limited probabilistic analysis which is what I consider the EWG analysis.

It's the shallow end of the pool. It's saying, okay, for those things for which we have a great deal of data and so it's hard for us to pick a number, but we have a lot of numbers to pick from, why don't we just use the numbers.

So for those things where there were dislodgeable residue data and 150 different points, use the 150 different points. Their approach was just to take the data sets and sample randomly with some sort of, I gather, Bayesian idea of how often you should sample from this data set versus that data set and for three or four parameters.

And the rest of the parameters, which were dominated by uncertainty, they fixed. And then they tried in some cases where there were more than one firmly held conviction for a particular parameter, they ran the estimate both ways. And I think one-to-one versus 4.6-to-1 for the hand-to-surface ratio is an example.

That's a wonderful exercise. It was very informative. It also informs you kind of how the maximally or highly exposed child compares to a median one. And how your various parameter choices, where you didn't have data to support an empirical distribution, impact the result.

I actually believe that, however, the goal should be a full Monte Carlo which includes distributions for both parameters dominated by variability and those dominated by uncertainty. And the ones that we discussed and will continue to discuss in this meeting have primarily been the ones where one person believes this, one person believes that.

I don't have personally have any problem with building distributions based on expert judgment. And we do that in our brains and then try to focus it down to a number. But, actually, we have found when we have done these kinds of analyses that if you talk to people and you interact and you describe, well, how does that distribution grab you, you can have a uniform distribution between your lowest estimate and your highest estimate. Or you really think it's around .4, but it could be as low as .2 or as high as .7, how about a triangular distribution, trapezoidal distribution. There's a distribution for any notion about what the parameter might look like.

And then you put them in, you run the Monte Carlo, and you see the results. You run a couple of different distributions when you're uncertain what's the right one; you see how that impacts the results. It's an informative process.

So the main thing I want to give people the impression is this isn't where you find out what's the number, run, get the answer. This is something where you have to work through it; it's an analysis; it's a very labor-intensive analysis. But it's extremely informative, and it gives you a much better idea of the range of exposures that are likely as opposed to just a central estimate and an extremely high-sided estimate. So I think it's worth the trouble.

And I think that actually if you look at the Gradient analysis, which is deterministic, they had their estimates. And you look at the parameter estimates from the EWG analysis and the parameter estimates that were suggested by EPA, that you can begin to build uniform, triangular, whatever kind of distributions for the ones where EWG varied them that was because there was enough data to do an empirical one.

I mostly suggest -- well, I guess this is stepping ahead to Question 11 -- that you need to do critical evaluation of the data. Don't use all the data. Don't use the pier in California. That's obviously not representative of a playscape. The loadings are much higher for saltwater applications.

So you should use your brains about what data should inform

the distribution and then test your first assessments on the basis of the results of the first Monte Carlo.

DR. ROBERTS: Okay. Who else is own line for this? Dr. Heeringa.

DR. HEERINGA: I add just very briefly to Dr. Clewell's comments which I thought generally a fairly comparable impression to the one I had in terms of these data.

I decomposed the actual elements to sort of taxonomy of about seven or eight different sets of parameters or sort of state variables. But I think that the one area that definitely, as in the EWG simulation, I think that you want to bring in the natural variability in the population, not only in children's ages but their body weights and heights and you got a nice probability based sample for doing.

So as a basis for simulation, you start with a nationally representative of population of sampled children. So that gives you the body weight and the BMIs and everything else that you might want to incorporate there. It also gives you the region of the country that you live in so you could look at different regions.

In terms of other activity data, I think that in terms of the stream of information that we need to really do this successfully as

a composition that the time and the activity data for the children is where we're really short in terms of usable data sets.

There are some time-use studies. I'm aware of one from our own institute that looks at the child supplement to the panel study of income dynamics which attempted to get some diary data on children's activities during the day. I doubt that that is specific enough to get an actual playground use, but it would at least allow you to sort of get a sense that the amount of time in play activities outdoors is reasonable.

Now, what kids actually do when they're outdoors, I really don't know, other than observational studies. And I'm not familiar with those, so I can't comment there.

I think those are the areas where we see the greatest amount of uncertainty in this pathway. I think with regard to residue availability on surfaces and soils, I think Dr. Stillwell's work and Dr. Townsend's and Solo-Gabriele's work is a very good place to start with that.

Another sort of difficult area -- but I know that Natalie has studied very thoroughly -- are transfer rates to the child either in terms deposition rates but also mouthing activities. And, again, I can't add anything more there than what we currently have other

than that more data would be beneficial.

Finally, I just want to say that with regard to compositing all of this in a probabilistic risk assessment, that in a separate Science Advisory Panel, we've actually reviewed the lifeline and Calendex (ph) models for the Office of Pesticide Protection. And I think that those are fairly fully developed; and as a calculation and simulation, too, I think would be directly applicable to this problem.

I think John and I talked about this before as sort of calculation, data storage, input control of these probabilistic assessments of exposure that there are virtually ideal tools for you to consider, and I recommend that you take a look at them.

DR. ROBERTS: Dr. McDonald.

DR. MCDONALD: In view of our concerns that the deterministic model of Question 7 will overestimate the central tendency and seriously overestimate the high-end exposure, I think that a probabilistic model is worth developing, in particular, a high-end value can be given that is interpretable as a percentile rather than as an exaggerated upper limit.

The Monte Carlo risk assessment presented by Environmental Working group is a good start and illustrates what

can be done with existing data.

Information given to the Panel during this meeting indicates that more data are needed to characterize other sources of variation and there are more factors that need to be included in the model. We need a model more complex than the deterministic model of Question 7.

I will outline what additional studies I think may be needed. The EPA is planning surveys of playground structures and substrates. These should be executed as one combined survey of existing structures and their substrates to look for correlations between structure and substrate.

In addition, all possible covariates should be recorded in the hope that the unexplained variation in arsenic and chromium levels can be reduced from what we have seen in the studies shown to date. Covariates might include the following: Evidence of construction debris, such as sawdust in the substrate; nature of the substrate, clay, sand, et cetera; the source of the wood; age of the structure; condition of the surface, new, aged, worn to a shine; climate; and the list can go on from there.

There appears to be more variability in arsenic in and on the wood than the industry would like us to think, dislodgeable

surface arsenic, in particular. The data sets the Panel has seen show great availability within and between the many available studies. When a survey of existing playground is completed, those data should be used instead.

It is possible that wet-weather play and play on damp structures brings increased risk of uptake. But there seems to be no information other than wet hand, dry hand wipe studies.

We need more detailed information on the relative time spent on the structure and in the substrate. I expect that this will depend on the weather as children may, for example, avoid sand that is too hot or too wet.

Data on the correlation between arsenic, chromium, and the structure and its substrate will be needed to use this information.

The Monte Carlo simulation will allow occasional events, splinters and abraded ,skin to be included. Things like that are very difficult to put into the deterministic model.

Well, hand-to-mouth activity is well-documented. We need more information on the rate at which the arsenic on the hand is lost and replenished by contact.

Dermal exposure depends on contact. To use data on exposed skin is an oversimplification. Even hand contact may be

incomplete at any time. So the surface area of the hand is not enough to know.

The factors I have so far listed concern the structures, the substrates, and the behavior of the children. These are things that can be measured directly and the variation quantified.

Other components of the model, like transfer rates and relative bioavailability, for example, can't easily be measured and will be included in the model with a distribution that describes our uncertainty.

It is important to distinguish between natural variability and the uncertainty of coefficients when we come to interpret the model.

Ultimately, there needs to be an epidemiological study that does a reality check on the predication to the model, perhaps arranging for a sample of children to play in a CCA-free environment for several months and comparing some measure of arsenic uptake with the same measure in a matched sample using existing CCA-treated playgrounds.

DR. ROBERTS: Other comments? Dr. Clewell, then Dr. Smith.

DR. CLEWELL: Well, actually, I did have a comment; but I

was pointing at Dr. Kosnett. He had his hand up. But I will take advantage of your misapprehension there.

I forgot to mention one of the things I thought was very nice about the Environmental Working Group analysis, and that was their following a child from age one through six. You could then embed age dependent on functions like mouthing behavior within the Monte Carlo. And I think that's a real advantage for something like this where it's wrong to try to ascribe all the range of behaviors to a three-year-old.

DR. ROBERTS: Thank you. Dr. Smith, then Dr. Kosnett.

DR. SMITH: That was one part of mine, so thank you for making that comment.

I think the other two comments is just to underscore again that if we're going to be doing a probabilistic analysis, that I would really encourage you to pay attention to any sort of information about possible correlations structures. Some of that can be dealt with if we're following the child over time and having that linkage through there. But we've seen real problems when you ignore the correlations.

I have a question for Dr. Freeman as to when will her new data from the Texas study be available because I could see that as

being extremely valuable input into this model.

And before she responds, my last question is I hope that the Agency, or I encourage the Agency, to embrace the uncertainty part of this analysis. In the past, the Agency has been much more interested in the variability part rather than the uncertainty. I think the uncertainty is incredibly important here to help us focus where we need research and where we need additional information. So that's going to be an important thing to be looking for.

DR. ROBERTS: Dr. Freeman, did you want to respond before we move on?

DR. FREEMAN: What I can say is that a preliminary presentation on this data is going to be given at ISEA in South Carolina in two weeks by Cathy Black. And we hope to have most of the data completed for publication purposes by the spring.

DR. SMITH: And can I, just as a point of clarification, that these data are going to, for the first time, give us the hand-to-mouth behavior for both outdoor environments and indoor environments. It's going to be obviously a much larger number of children. Anything else you want to mention about it?

DR. FREEMAN: Yes. It's outdoor environments, indoor environments, and longitudinal study; so we're following the kids

for two years.

DR. SMITH: Great, great, great.

DR. ROBERTS: Good. Dr. Kosnett.

DR. KOSNETT: I just want to echo what Dr. McDonald said but maybe even in a stronger way. I really thought it was surprising that with all we're doing here and all this discussion that there really isn't data that I'm aware of that's been discussed on urinary arsenic levels in children who have been playing in the playgrounds. It's been a relatively robust measure of exposure to or absorption of soluble arsenic.

And it would seem to me not to be very difficult even to get a small study together. You made reference, Dr. McDonald, to the Monte Carlo that was generated by the Environmental Working Group. And, you know, based on what I thought I saw in some of those risks and the exposures that would be associated with that that would be pretty readily apparent by monitoring not an extremely large number of children. I think it's doable. I think it could be done quickly. And I think would really help to shed some light on this whole issue, and I would recommend it strongly.

DR. ROBERTS: Actually, I think there is a lot of attractiveness with the idea of that study. But I don't know that

the difficulties of that study should be underestimated. I think a study could be done quickly, but I think a study that gets estimates of exposure with high confidence would have to be done very carefully.

We can talk about that. I think, perhaps, at the end of the day today. I think it is an attractive idea. Maybe we can sort of think about that and how that might be done and, you know, sort of what the caveats and the strengths of that might be. But let's do that later on.

Dr. Styblo.

DR. STYBLO: Just a couple of words to back up what Dr. Kosnett said. If you do urinary analysis, and it makes a lot of sense to me, please do food speciation of arsenic in urine. If you can arrange speciation all the way to oxidation states, it would be helpful because we will all evidence to believe that trivalent methylated species in urine could be markers of other adverse effects, carcinogenicity. You can refer it to labs like Chris Lees, of Canada, or Rose Marie Delaraso (ph) in Mexico City.

DR. ROBERTS: We can make that a part of our discussion a little bit later on today.

Let me ask. Dr. Vu, I got the sense that maybe you were

looking for something a little more specific in terms of recommendations on sources of information. Maybe that the wrong impression.

DR. VU: I think I'm just conferring with our colleagues here. I think the recommendations the Panel collectively have made is a very sound approach and certainly the Agency will consider the approach you talked about.

It's always the level of detail, of course, as Dr. Clewell said. We have to use our brain as well as look at data, et cetera. And we will consider that.

And on the issues of recommended research, certainly, as Dr. Roberts said, we will be appreciative to spend some time and talk about some of the key research needs that you think really have major impact into the ground truth, whatever the validation. So I think if you can spend some time, that would be very worthwhile for the Agency. Thank you.

DR. ROBERTS: Okay. Yeah, I agree with Dr. Clewell's comments. I think that the approach that he outlined is sound. I don't know that we can go into a lot of detail here in terms for this use this distribution; for that, use that distribution. I think it will be a process as he described of trying some different things and

seeing what you get and learning from that.

Is there anything that anyone on the panel would like to add before we move on to the next question? Dr. Smith.

DR. SMITH: I guess in terms of specific distributions, the only one that I, otherwise in asking you to use your brain, which I know you will, is that what I feel strongly about is that I do feel strongly that I would really like to see you try to incorporate the new data that Dr. Freeman is hopefully going to be coming out with soon as opposed to the current data on hand-to-mouth behavior.

DR. ROBERTS: Okay. Anything else before we move on to Question 9?

DR. EDWARDS: Question 9 has to deal with the lack of Agency data for use on transfer of residues from wood surfaces to skin. So we are asking, we assume that a one-to-one relationship applies to the transfer of residues from wood to skin. The Panel is asked to address whether this is a reasonable assumption, and, if not, to provide guidance on other approaches. We had used the turf residue one-to-one as a surrogate.

DR. ROBERTS: Dr. Freeman.

DR. FREEMAN: The answer is no.

DR. ROBERTS: With the microphone this time.

DR. FREEMAN: Okay. What I said is "the answer is no." It's not adequate. One of the things that is very frustrating about this project in particular is that at this point we have no data on how you would define the residues that are on these boards, whether we're talking crystalline structures, wet, oily, dust particles, things that are bound to dust or sand, you know, particular-size distribution, we have nothing.

Given that, we have to look at other people's data in terms of transfer and what we know. And I will talk about dry particles because that's what I'm most familiar with.

What we know with dry particles is that there is a limited size fraction that adheres to hands. That you can actually pick up some fairly large particles on the fingers, but they fall off, but that fall off. And that, typically, the sizes of the particles that adhere to hands are under 100 microns. In fact, there is some data that suggests that it is under 60 microns.

We were presented with some data by Dr. Stillwell yesterday that had a very small set of data which suggested that the transfer was somewhere between 30 and 87 percent.

The data from SCS that was presented to us had a range of 2

to 74 percent, depending on whether the wood was fresh CCA, aged CCA, or CCA wood that had been treated in some way. One-to-one was never an issue in any of these studies.

Charles Rhodes in his work came up with transfers of 48 to 76 percent. What we're getting is ranges. The SCS data show that there's was enormous variability from hand to hand on the same boards.

I don't think one is a good number. I think you're going to have to work with the range, which gets back to our whole probabilistic business again.

So that's what I had to say.

DR. ROBERTS: Dr. Hopenhayn-Rich

DR. HOPENHAYN-RICH: Well, first of all, thank you, Dr. Roberts, for sort of getting me off the hook because I had been assigned to lead this question; and I'm very appreciate because it really is quite completely, I might say, outside my field expertise as an epidemiologist. So the few things that I was going to say were pretty much covered by Dr. Freeman.

I would also just like to add that with respect to the SCC report that I reviewed, also, in addition to there being a lot of variability within each group, you have groups like aged

CCA-treated wood and then sealed treated wood. So I wondered what happened with aged, sealed, treated wood and all the other possible permutations among the different types of woods.

But I will let, at this point, Dr. Kissel, who is also much more of an expert on this topic than me, continue.

DR. ROBERTS: Thank you. Dr. Kissel. You're going to have to use the microphone, sorry.

DR. KISSEL: Part of my objection here is -- actually most of my objection here is conceptual with this approach. I think you mentioned that you were using the SOPs that were presented in '99 or sometime around then that had this transfer equation in it. And this notion of a transfer efficiency, I think, is potentially misleading. And the issue that had come up then and which points out one of the shortcomings is that things that are contaminated that you contact don't necessarily have larger surface areas than the hands.

And, specifically, the issue then -- and there was paper published a while back in which large doses to children were estimated on the basis of exposure to large residues on toys. But the toys actually were smaller in surface area than the hands. And why the calculation was done then violated conservation of mass

and made the toys produce pesticide to create loading on hands that were larger than the toys were in the first place. And that's not a good way to do mathematics and do modeling.

And so I would recommend that this particular equation be abandoned. I actually recommended it when I was on that SAP in 1999. And I'm recommending again that you toss it out and find a different way to do this calculation because there are situations in which you wind up producing mass out of thin air, which is just generally bad form.

On top of that, I think calling it efficiency is just misleading because the surface area of the hand and the surface area of the environment that it comes in contact with can be very different. And what it really is is just a ratio of a hand concentration to some surface concentration which was of an environment which could be very different in scenario to another scenario. There's no real reason why those things should match up nicely.

You could easily postulate cases in which the resulting hand concentration in the hand loading actually got to be much larger than the environmental loading. And one of the comments yesterday or the day before was that a 150-percent number didn't make any sense because it was too high, but you could easily get

that sort of a result depending on what kind of scenario you're talking about.

And the problem is that people think of a hundred percent as being the top efficiencies. But the way this efficiency is defined, in fact, there is no limit on the percent that you could conceivably get.

So while I guess I agree that there's a problem with the data and picking a specific number out of it, I think there's a bigger problem here that conceptually this is a bad way to go at this issue.

DR. ROBERTS: Dr. Smith.

DR. SMITH: I'd like to follow up on Dr. Kissel's comments on concern about the conceptual approach. And I think what I would like to do is use this as an opportunity to emphasize some of the points I've made over the past couple of days.

The first one, to begin with, is this notion of a transfer efficiency is one -- and I think I've asked this several times and I think it's been confirmed -- no one has done a study to show us that the transfer efficiencies are constant as a function of surface area wiped. That is an underlying assumption in the way you're apply this.

There are lots of different, you know, studies that are out there. Some use 100 centimeters squared. Some use 200. Some use 400. Some take hand samples and normalize to the surface area of the hand. Others take them normalized to the surface area of the hand swiped. There is complete chaos in the data sets out there. And there's no reason to believe that the transfer efficiency is a constant function of the surface area.

So one thing that you've got to do is, in the studies you're planning, you need to go out and investigate that. For whatever method you're going to use, you've got to convince us that whatever transfer efficiency, if you're going to employ this conceptual model, which I have doubts about, that you've got to show us what it is that's a function of surface area that's been wiped. And you may have to do this for damp versus dry.

Then if you're going to do the current approach, which is assume this one-to-one or whatever you're going to assume, you need to generate empirical data to defend that.

And, so, for example, right now as I understand the planned study you have, you're going out to collect additional data jointly with Consumer Product Safety Commission. It's my understanding that there is no intention to get any hand data at this time. But

that's crucial data to get if you intend to validate the model that you're proposing to use.

And, again, I have my doubts about the model. But if you're going to go to that approach, it's very important that you do that. So I just want to emphasize that I have no knowledge whether the one-to-one number makes sense or not. I've tried to take some of the existing sets that are out there where we have both hand and wipes, some of it's arsenic; some of it's pesticides. I don't see a lot of support for the approach. And I would encourage you to play that game as well.

But I really would like to see much more in the way of method development to underlie this approach with your acquisition of new data.

DR. ROBERTS: Some good comments so far. Anyone else like to add to this?

DR. DANG: Chairman, this is Winston Dang. I agree with Dr. Kissel's and Dr. Smith's point. It's the worse-case scenario under this kind of assumption is kind of much, much overestimated. I mean, not realistic.

But if you look, as I mentioned yesterday, most studies for so called "transfer efficiency" right now is from (inaudible)

surface to another surface. So the (inaudible) surface to another surface, we can estimate how much amount transfer to the other surface. That's most of agriculture work on the turf, is put on the toys or furniture we can estimate it.

And Dr. Keeser's study in 1998 talking about from the soil, how much to the mouth or other. That number amount we have no -- right now we don't know exactly CCA from wood surfaces because the wood surfaces impregnated it into the wood. On the surface, is residue amount. There we have to assume if it's 100 microgram per 100 square centimeter having been wiped onto the clothes or wiped onto the hands.

I don't know if I'm clearly able to explain to everybody or not. Because so far in our concept, it is we have no data to show the real true amount of the residue on the wood surface. Is it same amount from the wiped test that is showed here. So far, this is the best we have that used that kind of assumption on there. But I understand that that's overestimate. And so we are seeking for a (inaudible).

DR. ROBERTS: Thank you. Dr. Smith.

DR. SMITH: I would just like to emphasize that I don't know think you know if it's an overestimate or not. You know,

when I've looked at the empirical data that's out there, I can get it to go twofold either way, depending on the surface and depending on the substance that's looked at.

So I really don't think you know whether you have an overestimate or not. So I would be very resistant to classifying it as being overly conservative. Because remember, what you're doing right now is you've got wipe data, you take a block of wood, you wipe some surface. Clearly there's accumulation onto that. You normalize it over that surface area.

Under your current model you assume you put the hand down on the surface, there's no consideration to how much the hand is contacting that surface, how long, and you're allowing for absolutely no accumulation onto the hand. And we know we have empirical data that there is accumulation on the hand. We also know that it's very nonlinear.

So I don't know how far you're off, but I do know that you're off. So I would, again, strongly encourage you to, in the new studies you're going to be doing, collect data that will help us better understand that.

DR. ROBERTS: Okay. Well, final call for comments on this particular question. Dr. Ginsberg.

DR. GINSBERG: Would it make not sense to try to move toward the direct measurements of the hand on the wood rather than using the swipe data? Why deal with this factor at all if we can generate new data in this new round of testing. And we already have some data from SCS. AWG showed one overhead that had some data from Maine that I think Dr. Smith had generated, as well as the California data and the SCS Data which is direct measurements on hand uptake which doesn't involve this intermediate step of this calculation.

And if we had opportunity for new data as has been recommended by others, maybe to use that as the primary data bases and then use the swipe data with other materials as sort of backup to support whatever distributions you want to use. But maybe that should be the primary way to go.

DR. ROBERTS: Dr. Hopenhayn-Rich.

DR. HOPENHAYN-RICH: My question is a clarification of what you just said, Dr. Ginsberg. And it might just be a product of my ignorance of this topic.

But if you only do the hand and you're trying to get at a relationship between what's there and what gets on the hand, what are you going to compare what you get on the hand to? What the,

you know, true concentration is on that board or that structure or whatever it is that the wood is? What is your comparison?

DR. ROBERTS: Dr. Ginsberg.

DR. GINSBERG: For the risk assessment purpose, the relevant environmental measurement would be the concentration of loading of arsenic or chromium per centimeter squared of hand surface area that is getting into a mouth. So what is on a filter-paper wipe, which is not going into any child's mouth is removed at least one step from what we need in a risk calculation.

What is directly relevant for a risk calculation is what a hand can pick up. Now, I'm not saying that that's such a straightforward thing to measure because, as we have said before, that there's variability. You could go and wipe a small area, and then you might -- well, actually I think the issue that Dr. Smith was raising is important to look at.

But I think that as long as on a board surface area you do the experiment such that you reach some kind of equilibrium, and that assuming in this three-minute reloading or if it's nine per hour, what is that time limit reloading. But whatever that reloading period is, if you run your experiments so that somebody loads their hand for that three minute interval, whatever, see what you can

actually pick up with the moistened -- assume that the child's hand is moistened because of hand-to-mouth activity or because their palms are sweaty, whatever.

What do you pick up in the three-minute loading period on these different kinds of deck surfaces. Maybe that is irrelevant. You know, I'm just brainstorming. But maybe that's a good way to do it rather than this swipe and then this calculation.

DR. ROBERTS: Well, I think some hand-measurement data, in my opinion, are going to be important whether they are, as Dr. Smith suggested, essential for verifying or validating whatever model that you pick or whether they become the primary means of collecting data. Dr. Clewell.

DR. CLEWELL: I think that Gary has a really good point. Well, what we really want to know is the hand concentration, associated hand-surface concentration, associated with contact from the wood; and we're trying to infer it from some sort of measure of wipe concentration resulting from contact to the wood.

So that there is existing data. I know either Dr. Townsend or the other person from Florida described some yesterday that they had recently collected. There were two different SCS studies, one is '98, one in 2001. And so that data could be used to try to

provide a correlation between them.

But it seems if they are going to do a new study, they could, as part of that study, do a small subset of the places they're going, a comparison of hand-to wipe if they can't really do a hand one in every location. It might be logistically difficult. They could do their own correlation for the methods they're using in order to be able to do a better inference for the full data set which could still be done with wipes.

DR. ROBERTS: Dr. Smith.

DR. SMITH: I would like to follow up on that. I mean I agree with it, generally, but I think I would take it even a step further. I think what we would really like and what would go very, very nicely was Dr. Freeman's new data would be if we go out and actually get wipe samples of children hands on various playgrounds. It wouldn't be a difficult measurement to get. It will be a lot easier to get through an IRB than some of the other studies that we're thinking about amongst this group.

And I understand the desire for a wipe test because it gives us this sense of control. We can go out and reduce the variants and we can really look at all these wood factor issues. And it might be nice to have that.

But for the analysis we want to do, we really need to embrace the variability that the children provide us because the kids are out there. Sometimes their hands are wet. Sometimes their hands are sticky. It's a very variable world out there. And that's the information we need to capture.

And as far as I know, I have the one data point on a child's hand at this point in time. And that doesn't strike -- it would be rather hard to make a distribution of that.

So I would strongly encourage us to be thinking about going and collecting data on children's hands in actual playground settings.

DR. ROBERTS: I like your suggestion, personally. Any other comments?

DR. GINSBERG: That's what I was going to say.

DR. ROBERTS: Dr. Ginsberg likes that suggestion, too.

Anything else on this particular point? Dr. Vu, have we been reasonably clear on this one?

DR. VU: I'm seeing my colleagues nodding their heads. Yes. Thank you.

DR. ROBERTS: Let's take a short break, and I mean short, like 15 minutes. Take care of business and come back at 4 o'clock.

That's six more to go.

(Brief break.)

DR. ROBERTS: First off, I have to apologize to Dr. Lees. Shortly after we had completed our discussion on Question No. 6, he had asked for the opportunity to sort of reopen it briefly to make a comment, and I forgot about it. We got started into 7 and then 8 and then 9. So with my apologies, let me go ahead and reopen, briefly, Question No. 6 to give Dr. Lees the opportunity to make a comment.

DR. LEES: Thank you. Actually, I'd just like to make a comment for the record. And as you remember, or maybe you don't at this point, at the end of the discussion on chromium and dermal issue, it was stated that the industrial population might be a good indicator of dermal effects and that may or may not be so.

I'd just like to put out the caveat that especially when you're dealing with sensitizers in industrial populations sensitive people select out. So that in a cross-sectional study even though there had been lots of sensitized people, if go out there and look, you may not see them. So I want to get that caveat on the record. Thank you.

DR. ROBERTS: Thank you very much, Dr. Lees.

I, also, want to do a small go-back on Question 9. I was hoping we could have all of the panel here.

We were asked about probabilistic risk assessment and were asked specifically about some of the inputs and those kinds of things. I think it would be useful, perhaps, also, for us to find -- and we've talked about other studies and things that be incorporated into a probabilistic risk assessment.

I'm doing a go-back on 9. No, I'm sorry. Go-back on 8. I'm sorry. Go back on the probabilistic risk assessment.

I guess it would be useful, I think, for the Panel to give the Agency, since they asked us about distributions and information, our impression of whether or not the information is there for them to proceed with the probabilistic risk assessment now, immediately, or would we advise that they wait, for example, for the results from this collection activity, hopefully modified with some recommendations as well as perhaps the Freeman data. I mean, we had a lot of suggestions about ways that could enhance this.

Are these sort of refinements, or are these important pieces of information that should be incorporated into the analysis? I'd like to get some comments and feedback from the panel members

on that. Dr. McDonald and then Dr. Smith.

DR. MCDONALD: Certainly, the things I suggested I saw as essential refinements but not to prevent one from stating to work on what's available now.

DR. ROBERTS: So to be sure I understand, you think that they could perhaps conduct the analysis and use the analysis based on the data they have now. I guess I'm not talking about delaying beginning to work on it. I'm talking about conducting an analysis. I just wanted to be clear on that.

DR. MCDONALD: We can make suggestions for what studies have to be done, but we have no idea how long it's going to take them to do it, even to get approval let alone carry it out and get the results back.

DR. ROBERTS: Thank you. Dr. Wargo and then Dr. Smith.

DR. WARGO: After you.

DR. SMITH: Thank you, you're most kind. Andy Smith, State of Maine.

I guess I would look -- it depends on the inputs. Some of those that we have reason to believe are going to be available soon, such as Dr. Freeman's, if I understand correctly, new data, not to put any pressure on you.

But, you know, to me that data set is, you know, so much stronger, as I understand it, than the current data set, which is four individuals, that I would, you know, believe that the analysis ought to wait for that. And I can imagine that you've got more than enough work to do to keep you busy between now and that becoming available in some form to be used. So I don't see that as a major limitation, I hope. So that's one data set that I would really like to see you use.

As far as some of the other data, for example, more information on your planned study. That's a more difficult one, but I guess I would, depending on how our discussion goes at the end of the day about studies.

There's a part of me that would like to see you wait on that as well, only in part, because I'm just very, very concerned, as I've said, that I don't know what to make of the assumption of a constant transfer efficiency. I really don't know how to use the existing data that's out there right now, unless you wanted to use the existing hand data as a place to start to just start to begin these analyses. But in terms of using the wipe data, I just don't know how to use it at this time.

DR. ROBERTS: Thanks. Dr. Wargo.

DR. WARGO: I think the process of model development is going to take some time. I would be surprised if it were designed in six months. And I think that you're always going to want to improve components of the model and improve all the different factors and parameters that you're trying to measure.

So, once again, my view of this is that it's a living model, so to speak, and that it will improve in quality.

And Dr. Clewell had it right on, I think, when he said that the purpose is not to spit out a number at the end; the purpose is that it's an educational device, it allows you to understand the relative significance of different factors.

DR. ROBERTS: Thank you. I would just add at some point it may be a living analysis, but at some point for regulatory purposes, you say it's done. or at this point, we're going to take the results of those and make some kind of decision. And I think that's what the Agency is kind of faced with.

You know, they could conceivably probabilistic conduct a probabilistic analyses tomorrow, and it probably wouldn't take that long to get it done depending on the data sources they use and how long they work at it and how much goes into it.

But, again, I'm trying to get some feedback? Would that be a

good one in our opinion, or are there any sources of information or other factors that would go into that? Yeah, Dr. Smith.

DR. SMITH: It's always an interesting discussion for me when we seem to invoke a much higher standard for wanting to go forward with a probabilistic analysis then we do for wanting to do a deterministic analysis.

If we're uncertain, we're uncertain; and we ought to embrace that uncertainty the best we can and try to incorporate it into our analysis. And if the data are very limited, you know, we need to try to make some way of estimating that uncertainty and including it in the analysis.

So I'm not exactly sure where I'm going with this comment. Other than I think we can go forward. But I don't think we should be putting such a high hurdle on saying we need to have the absolute best data set for ultimately characterizing the distribution.

DR. ROBERTS: Any other comments or other opinions on this? Dr. Heeringa.

DR. HEERINGA: As I mentioned in my comments, I think the two areas of weakness in a probabilistic assessment are the time and activity schedules of kids and how much real exposure

they have in terms of duration to CCA structures. And then the second is this transfer from the structure to the hand or ultimately to the mouth, I think, is another element in there, too.

DR. ROBERTS: Any other comments on this? Yes, Dr. Gordon.

DR. GORDON: As Dr. Wargo said, I think it's going to be a living, ongoing thing six months. But Dr. Heeringa said earlier you know in an Excel spreadsheet, 2 to the 6th, 3 to the 10th, whatever it's going to be. That could be done and useful now, I think. So I think they can do a deterministic.

DR. ROBERTS: Well, I think the question was, since we recommended so strongly that they do a probabilistic, are there data sufficient to conduct an analysis that may be meaningful for regulatory purposes?

DR. CLEWELL: I think Dr. Smith gave a good answer today.

DR. ROBERTS: Okay.

DR. SMITH: And I guess, again, we're still, unless we've heard something different. What I thought I heard was we would do a deterministic analysis as a screening level to look and see if this is an issue we need to focus on in greater detail.

And if that, again, remains the sole purpose of doing the

deterministic analysis, then I think those that have already been done are sufficient to get us there and we just need to procedure with a more refined analysis. If you're instead telling us immediate that you may take immediate action very soon based on, and want to take action very soon on a deterministic analysis, well, now you're saying you want something very different.

DR. ROBERTS: No. Please don't get that interpretation. We recommended strongly that they do probabilistic analysis. At the same time, we made a number of research recommendation or data-needs recommendations. And what I wanted to get from the panel is a sense for are we saying do a probabilistic after you get this information; or do a probabilistic now, but you also should consider doing this information that would provide a more refined analysis.

I'm just trying to present a clear picture on that. Yeah, Dr. Wargo.

DR. WARGO: I think I would do it now because I think that the act of putting the model together and analyzing the data will help understand which variables we need the better information for. So it's going to give us strategic guidance.

DR. ROBERTS: Dr. Ginsberg.

DR. GINSBERG: I think the activity of developing the distributions that are needed, especially some of the key ones that drive exposure, can be worked on now. Some of the data you may have to wait, for example, for Dr. Freeman's Texas data which may be an important data set for hand-to-mouth frequency.

But things like days per year, maybe there's other data sets that you can use and develop a distribution and check with different regional offices and say does this make sense for your region. What other, you know, to try to start becoming as data rich as possible now in some of these other areas where there's not going to be a new study, but you may just have to do some ground truthing with some of these distributions and say -- like Harvey was saying, some of it is professional judgment. And to start working along the lines of getting as much of the distributions that we can get a handle on, getting those now and then waiting for the new playscape study and the new hand-to-mouth study to finish it.

DR. ROBERTS: So I think I'm hearing proceed and with the strong preference for including data from Dr. Freeman, if possible. And I think I heard her agree to work nights and weekends, I think, to make that data available as soon as available.

DR. CLEWELL: Starting tonight.

DR. ROBERTS: Starting tonight. Very good. Anything else before we move on?

DR. SMITH: Now that I clearly understand what you were asking. I want to be just clear, again. I think I would have concerns about them going forward with an analysis right now that would use existing wipe data. I could see going forward if you wanted to try to make use of existing hand data to try to characterize some sort of distribution. But I just don't think we understand the wipe data well enough to use it in an analysis at this time.

DR. ROBERTS: Is that an are on which we sort of a consensus thing, or is that no, we're not sure.

DR. CLEWELL: I'd agree with that.

DR. ROBERTS: Dr. Gordon.

DR. GORDON: In reading the history of it in one of the environmental groups put strong emphasis on it. I mean a lot of us are academics, just came in in this one- or two-week period and were given this task and we're criticizing the heck out of it. But the process is really, really slow. I mean EPA is famous for that.

DR. SMITH: States, too.

DR. GORDON: States may more so. I feel a little bit

hesitant to say, wait for this data, wait for this data, wait for this data, because they have to move forward, hopefully, with the best at hand.

DR. ROBERTS: Okay. Great. Let's then move ahead with Question 10. Yes, 10. Which may be rendered moot by some of our previous discussion but let's go ahead and take it anyway.

DR. EDWARDS: Question 10 having to deal with the soil adherence factor. The Panel is asked to comment on whether the proposed adherence factor of 1.45 milligrams per square centimeter for hand contact with commercial potting soil is realistic as a value for use in estimating the transfer of residues from playground soil to skin in this assessment.

I would just also add that if we consider buffering materials, the adherence factor may come into play for those textures as well.

DR. ROBERTS: Okay. I had Dr. Adgate listed as lead discussant. Are you lead discussant, or is it Dr. Kissel?

DR. ADGATE: I'm going to lead very briefly because given that Dr. Kissel has done one of the major studies in this area, there's no point in me say too much. But other than to say that it's not a good number. He'll tell you why. Sort of the short and sweat.

I mean I think this is just yet another good example of why we should go to probabilistic modeling. And the other thing I found curious about this is to sort of specify to three significant digits, I think data that's this bad just doesn't make a whole lot of sense to me.

The other thing I'd like to emphasize is that I think this idea of doing it by age is important because it will allow us to look at these wet season or saliva-covered hand and things like that by stratifying the analysis by age.

And the other point that I think that is important is the surface area loadings have to be sort of normalized across the various body surface areas. I mean the number of 1.4 may be fairly close for the palm of the hands. It's within the ballpark is what I think John is going to tell you. But it's not a good number for some of the other 1,600 square centimeters on the body since you're talking about legs and arms and not necessarily the palms of hands. And exactly what number we sort of land on is it some measure of central tendency tends really is going to depend on the shape of the distribution. And I think John can probably inform us a little more about that. So I will defer to him.

DR. ROBERTS: Well, let's go to him. Dr. Kissel.

DR. KISSEL: Can I give a two sentence addendum to Question 9 which is relevant to this also? It just didn't get said.

DR. ROBERTS: Sure.

DR. KISSEL: The last recommendation was that we do hand wipes in the real situation to get the hand loadings on kids to go with the environmental measurements. That should be extended to other body parts because the scenario you've worked up, does include dermal absorption through other body parts. And those other body part loadings are likely to be much lower than hands, so you need some numbers from someplace else, also.

DR. ROBERTS: Good point.

DR. KISSEL: So, yeah, the biggie here is that the 1.45 was a hand number in kind of an extreme case, and it's way too high for other body parts. To give you a little perspective, for a normal soil, a monolayer coverage, complete surface coverage, it's actually not a monolayer because you get a mixture of particle sizes.

But complete surface coverage would occur somewhere between 2 and 3 milligram per square centimeter. So 1.45 square centimeters is something like three-quarters, 50 percent to 75 coverage of the skin. So look across the way at somebody and try

to imagine their face three-quarters occluded with dirt. And that's the load that you're talk about there.

You may see a kid like that every once in a while, but very seldom. And it certainly not a kind of an every day oh, I went to the part today, and I came back three-quarters covered with soil on all exposed skin. People don't get that dirty very often. So the number is quite too large.

Now, one rub here is this is kind of a specific scenario where you really want to know adherence to soil from the playground area as opposed to just the generic kind of number.

And I can't recuse myself from talking about my own work here because there isn't anything else to talk about when you get away from hands. So I won't. But the numbers for other body parts should be lower.

We generated some numbers from EPA that are in that Regs Part E document which is supposed to be coming up soon and has been coming up soon for quite a long time now. They generated an overall estimate which is based upon more of an annual average as a consequence of a variety of activities. And they weighted different data that we gave them and made a decision.

And I don't have a big argument about how they did it. But

it might not be directly applicable to this scenario because this is kids playing in a place with loose soil or something like a loose matrix of some kind as opposed to what all kids run into run as a consequence of their whole-life activity, which includes a lot of time inside and a lot of time on grass and things that aren't loose media.

So those numbers, the overall number that the superfund dermal work group people came up with is probably too low for these purposes. But you could, for instance, go in there and pick.

There's one of the populations that we sampled was kids in essentially a sand box sort of environment. It wasn't sand. It was sandy loam soil in landscaping timbers. And we put kids in it and had them play with trucks and toys and do those sorts of things. The kids were a little older. They're 8 to 12 instead of 1 to 6. But it was shorts and, well, actually, there was one set of long sleeve and long pants. But you could take those body part measurements out.

It's mostly driven by the hand numbers anyway. When you get a surface-area weighted answer, the hands are going to have the highest loading and they're 20 or 25 percent of the total. And so the number is going to wind up looking a lot like 20 or 25

percent of the hand loading as a weighted average of the total.

And that produced a geometric mean for that group in the .15 range at the median, and it was about 3 milligram per square centimeter at the 95th percentile by EPA's calculations. Actually, there weren't 95 kids in there so that's an extrapolation on the assumption that it's a lognormal distribution.

And that was in wet soil. So it should be a conservative case for these mixed conditions which would be dry soil, wet soil, rubber, and other kinds of media, whatever you're doing. My hunch is that that number would not be too bad. And it's the best thing that you can come up with right now because there are no ground tire kind of numbers that I'm aware of.

My hunch is that pea gravel doesn't stick to skin very well, so I wouldn't worry too much about that one. I don't think you'd underestimate the adherence of pea gravel.

DR. ROBERTS: Okay, Dr. Chou,

DR. CHOU: Dr. Kissel told you not only why, he also told you how. And I agree with him. This is probably a good enough number to work with for now.

DR. ROBERTS: Any other comments from other members of the panel?

DR. CLEWELL: Just could he repeat those? So that was a median of about .15 and a 95th percentile around 3.

DR. KISSEL: Yeah.

VOICE: In wet soil.

DR. KISSEL: It was a wet, sandy loam.

DR. CLEWELL: It was a wet, sandy loam.

DR. ROBERTS: Actually thinking about PRA, is there a distribution around that?

DR. KISSEL: The data sets are fairly small. But the assumption is that it's log normal and, at least, doesn't flunk those tests. You know, when you don't have too many data points, you tend not to flunk those tests.

DR. CLEWELL: Most things look log normal if you don't look closely.

DR. ROBERTS: If you don't look too closely. I concur. Dr. Kosnett.

DR. KOSNETT: John, I just want to make sure I understood something. The values that are being used that you are discussing, you're talking about adherence of soil to the skin. But the context in which this adherence factors is not for soil ingestion. That's being used by a default or maybe not a default, but a distribution

around 100 milligrams. This is just for contact with the deck, with the wood.

DR. KISSEL: Correct. Yeah, it's to get the dermal absorption data. No, this is for soil. This is not the -- the residue data, dislodgeable, would come for that stuff we were talking about under Question 9.

DR. KOSNETT: When you look at the scenarios that they have in the book, in this document from September 27, the "Child's Exposure to CCA-treated Wood," Scenario 3 is where they're using incidental ingestion of residues due to hand-to-mouth contact with CCA-treated wood playground structures.

That's where the hand-to-mouth issue comes in. On Scenario 4, Childhood Incidental ingestion of CCA-contaminated soil, that hand-to-mouth issue doesn't come in. It's just that --

DR. KISSEL: No. That comes from the 100 to 400 milligram a day number that is the standard for that.

DR. KOSNETT: So you're using this for just pure dermal absorption.

DR. KISSEL: This is dermal contact.

DR. KOSNETT: Okay. I understand that.

DR. ROBERTS: Dr. Hopenhayn-Rich.

DR. HOPENHAYN-RICH: Yes. I'm sorry to bring this up now, but it has some relationship with Question 9, but I guess it might have some relationship to this. In terms of wiping the kid's hands to get an estimate of exposure, Question 9 was referring to the wood, what came from the dislodgeable from the wood. If you wipe the kid's hands, how do you know what comes from the wood, what comes from the soil; and does it matter to make that distinction?

DR. KISSEL: I don't think you will know unless you find a play set that's on a surface where there's not loose media to run into, or you do some pretty excruciating pick with tweezers through the residue and sort out of the lumps of soil.

DR. HOPENHAYN-RICH: I just bring it up because the question was addressing the wood-to-skin transfer.

DR. ROBERTS: Yes. I think so. But I think it, again, it's measuring dosimetry approximate to the individual and, in a sense, it probably doesn't matter would be my initial impression. Well, unless the bioavailability is different.

DR. KISSEL: There is a potential for double counting here for dermal absorption. So you might want to look at play sets that are on asphalt just to get just the chemical residue numbers.

DR. CLEWELL: You really think the soil would --

DR. ROBERTS: For the record, this is Dr. Clewell.

DR. CLEWELL: Do you really think the soil -- I didn't think the soil levels on average would be high enough to actually make a big difference compared to the direct contact with the structure.

DR. KISSEL: Are we talking about the way the numbers turn out? They're smaller. If you knew what the soil concentrations were, you might be able to discount the soil as a player in the residue on the skin.

DR. ROBERTS: Any other comments on this question? Is the response clear to the Agency? Did we answer the question?

DR. VU: Yes.

DR. ROBERTS: Okay. Great. Let's go on to the next one, then.

DR. EDWARDS: Question 11 has to do with the variability of the existing residue data for soil and wood. OPP will need to calculate the immediate term and possibly long-term exposures in this assessment using available wood soil residue data.

The Panel is asked to recommend a credible approach for selecting residue data values for use in OPP's risk assessment. Taking into consideration the inherent variability of the data sets,

please advise us on which values are best for representing central tendency and high-end exposures. Also, the Panel is asked to discuss the feasibility of combining data for a probabilistic assessment.

DR. ROBERTS: Let's see. I believe, Dr. Leidy, are you the lead.

DR. LEIDY: Yes.

DR. ROBERTS: Actually, you've been much too quiet today and I look forward to the opportunity to hear form you.

DR. LEIDY: It's so much out of my area, that I don't know where to begin.

What I would like to do is begin with your third assumption if it's feasible to use data from all sets. And I took that to mean that you want to combine the data from playgrounds and data from decks. And we do not think that should be done, nor do we think as, Dr. Clewell pointed out a while ago, that we should use data from piers or from walkways across water areas and wetlands, that type of thing.

But the data are scarce. And looking at what you people gave us essentially last night, there were two relatively reason reports doing playground equipment, Rietal, et al., from '91, where

they looked at 10 playgrounds. This was a draft report to the Health and Welfare of Canada.

These data were well documented as far as descriptions and drawings of the playground equipment, where the soil samples were taken, a characterization of age and that type of thing. So we feel this could be a data set that could be used in your initial analyses.

The other, which we did not get this Malcom Pierney, 2001, a report, "Results of Soil-sampling Analysis of Playground Structures." This was a draft appendices prepared for the American Chemical Council. It deals with four playgrounds in the U.S. I don't know anything about it, although it was mentioned in a couple articles that the data that were presented were relatively good.

As far as decks, the study by Stillwell and Gorney from '97, in the Bulletin of Environmental Contamination and Toxicology, that was seven decks, talking about their contamination.

The study by the Scientific Certification Systems in 2000, study of arsenic leaching in the soils underneath CCA-treated wood decks, prepared for Osmose. This had 10 decks. Five of those were between 5 and 10 years, and 5 were between 10 and 15

years. The data from this from this study are well-documented and you people gave that to us last night.

The third one is a very large report from the young lady that sits beside me, Dr. Solo-Gabriele and Dr. Townsend on metal concentrations in soils below decks made of CCA-treated wood, where they looked at 9 structures in the Gainesville, Florida, area. And these data were well-documented, also.

The reason that we feel that these should be separated is because you're only residues seem to be higher under decks than they are under children's playgrounds, the play equipment. And so based on these and looking at this study that you people are getting ready to start, we feel this study should be greatly expanded.

We think that you should actually look, in addition to the 25 playgrounds areas in each of the three regions that you're selecting, that you should also look at 25 decks and combined playgrounds or these play structures in those same houses in each area.

And the types of data that we feel that really are going to increase your knowledge and the ability to use the various models to determine what exposure is, should include things like the soil

types that are selected in this study should be those most commonly found in each region.

I mean if you're in the Piedmont area, for example, where you go from a sand to sandy loam to a clay loam to a clay and so forth USGS has got all these maps, as you folks know, and they would be able to give you , I think, the most representative soil type in the various regions that you're going to take.

I don't think that anybody here wants you take all sand, for example, or all sandy loam. I assume that, based on the three regions that you're selecting, that there would be predominant soil types in those.

We feel that when you select the playground or home or whatever that you get a detailed or as detailed a history as you can on these, including type, age, has it been treated, and so forth.

We feel that the soils that are collected should be representative. And, you know, as has been pointed out that the residue levels of soil are going to differ greatly.

And so I think as was done by Dr. Townsend and Helena, that you need to take those samples from the locations where you expect to find high residues but also randomly from areas where you're not going to expect high residues just to ensure that --

because you're not going to have uniform distribution that, consequently, the residues you find are going to vary.

We feel that the determination should include the organic arsenic species, the review article you gave us in Reviews of Environmental Contamination and Toxicology discusses and has been discussed by some of the experts here that these species are formed by microorganisms and so forth, and they might actually be present in the school on these playgrounds and so forth.

And I think that if you're going to look at speciation, which we feel is required in this type of study, that you also look for the organic species in addition.

We think that the soils that you take have to be totally characterized: Clay, sand, silt, pH, conductance, moisture, organic matter content, de dah, de dah, de dah. So that these people here who deal with movement and so forth will have a better idea of how these residues are actually migrating down and perhaps out to the side and so forth.

We feel that you should take borings from sections of the playground equipment where known activity occurs. And you can do this by videotaping these kids. This has been done. You can video kids playing in these playground. Why take a wood sample

eight feet above an area where the kids are down around two feet or three feet or something like that.

As was sort of pointed out yesterday, wood today is not what wood was 15 years ago. You have lots of knots. You have rings and so forth, are to my way of thinking are probably the reasons why you will see such a range of values in these woods. I think they talked from like .17 pounds per cubic foot to .37 in one board.

So I feel you need to take those samples from areas where activity actually occurs, and the best way to do that is film these kids playing in these particular structures.

We think that the wipes from the heavily used areas and from the areas indicating runoff potential should be taken. And we think that you might consider, and it was pointed out it's difficult but it can be done, that you consider collecting hand and leg rinses from a representative sampling of the children playing on the equipment. That gives you the real world data that are required, or at least we feel they are required.

We think that all these buffering materials that have been mentioned should be collected, including borders around the various playgrounds and so fort to again ensure that a kid sitting on an area for a prolonged period of time or resting on their knees

or what you aren't being overly exposed to these.

And I know you can consider that the dust and so forth is minimal. The Agency is very interested in pm 2.5 and lower. And dust is generated in this these things and these kids will inhale this. And it might be a very minor thing. But while you're collecting all these samples, it's something that you might consider.

And will now pass to my two colleagues.

DR. ROBERTS: Very extensive response. Well-stated, Dr. Leidy. Thank you. Dr. Adgate. Do you have anything to add?

DR. ADGATE: A lot of what I would have to add -- I've written more than a page of highly eloquent text, but I won't read to you that is largely already been said. So I don't think I need to add a whole lot. A lot of it has to do with the process of probabilistic analysis.

The one little caveat I would throw in that I'm not sure has been said is that we shouldn't -- when that gets done, we shouldn't be mixing these point estimates and distributions if at all possible because that does sort of strange things to the process and you'd be better off picking uniform distributions in those cases.

Other than that, I will punt to Mr. Clewell.

DR. CLEWELL: I guess I focused on the other two questions. There were actually three, as Dr. Leidy pointed out in here. The feasibility of combining data from individual data sets is clearly -- I won't say it's straightforward. But it has certainly been done, and there are considerations for it. But it's not very complicated and there are published examples of building a global distribution from individual ones.

As far as representing central tendency in high-end exposures, I don't know. We may have done away with that by pushing them to probabilistic.

I would point out that the fellow I work with, Kenny Crump, has published a paper says the arithmetic means is the appropriate measure for central tendency for health effect concerns.

DR. ROBERTS: Okay.

DR. CLEWELL: As opposed to the geometric mean or median. If you want to read that paper, I cite it im my written comments.

DR. ROBERTS: Okay. Dr. Smith.

DR. SMITH: Am I correct that on Question 11 when we're asking about selecting residue data that this also applies to not just the soil data but the hand-loading data as well; is that correct?

MS. AVIADO: It's a question specific to the residue for the wood and the soil.

DR. SMITH: Okay. So then I guess I would ask that the comments I made earlier about my concerns with the hand-residue data, the hand-wipe data, would equally apply here.

And what I would just add to it is that in addition to not having yet to establish that the transfer efficiency is constant, which you would need to do if you want to go forward with your approach.

We also, as far as I know, at least for this specific application or this dislodgeable chromium and arsenic issue, there's been no -- I don't think, and people can correct me if I'm wrong. I don't think there's been any or much in the way of side-by-side comparison of methods.

As you know, we've got some methods where they're doing wipes with Kimwipes that are just held by the hand. We've got more elaborate methods such as those done by Dr. Stillwell. And to his credit, he's probably done more method development than anyone in terms of trying to get a sense of how much removal efficiency there is.

So on the other hand, we have methods like that. The

methods differ in terms of how many repeat wipes they do of the same surface; what the pressure is applied; whether it's damp; whether it's dry. All this is represented in these data sets that you would want to combine or that you're asking about combining. I don't want to be judgemental.

So I would have considerable concerns, since we don't understand what's going on, as what we would be capturing by modeling those data sets. I think the Environmental Working Group people made a statement that they felt, well, perhaps that helps characterize all of the things that are going on in the real world. I don't know whether that's the case or not. I don't know what to think about that.

So I just would be nervous about combining across the wipe data sets when we have so many different methods and so many different approaches. And we really don't know how to compare them at this time.

DR. ROBERTS: Dr. Ginsberg.

DR. GINSBERG: Yeah, to try to be specific as Dr. Smith is heading in that direction. I think that for the hand wipe, if somebody right now just do a run, take a shot at it, that if you wanted to be entirely consistent and just use hand-loading data,

that the Berkeley data from the California Department of Health would be a reasonable data set. Although it's not very extensive, but at least it does represent a playscape in use with use with hand-loading information.

I would query Dr. Smith about his data, his hand-loading data and whether he felt that that would be of a high enough quality right be put right into a risk assessment, some preliminary risk calculations. And then, of course, we have SCS hand-loading data.

Regarding soil data, my thought is that some kind of a temporal factor needs to be brought in for play activities directly underneath a play structure. I know my kids spend lots of time, especially in hot, sunny weather, in the shade underneath a platform or walkway on some of these structures which might be higher, you know, the high end of the soil data versus sort of out in the middle of the area away from a play structure which would tend to have the lower data.

So I don't know if there is any videotape of kids and how much time they spend in different parts of a playground, underneath the structure or away from it. But some kind of a factor, I think, needs to be brought in to make good sense out of

the dichotomy in soil results you'll get near the structures versus away from the structures.

DR. ROBERTS: Are there any other comments?

DR. CLEWELL: Am I supposed to respond to Dr. Ginsberg?

DR. ROBERTS: It depends.

DR. CLEWELL: As you're aware, Gary, our view of our data set was that it was a pilot data set. It was much more direct. It was a single deck, a single individual. There's not that many samples. In total, we maybe have 20 or so on this single deck. But the emphasis of it was really much more to try to understand the loading phenomena than it was to try to get a range of numbers.

As we described the experiments to try to look at what the effect of distance in terms of how much you wipe, wet hand versus dry hand, repeat rubbing of the same surface, is there any sort of diminishing of what's on the surface, et cetera.

So it was much more along those lines of just try to understand the phenomenon. That may be of use for people. But in terms of actually providing us another data set, I don't think it's as robust enough for that. It was really intended for other purposes.

DR. ROBERTS: Okay. Are there any other comments?

Should we see if we can sort of synthesize this or are they reasonably consistent comments? I think I've certainly heard from Dr. Smith some reiterating reservation about applicability of the wipe data in general and concern about combining data sets. And I would have to agree that it wouldn't be clear whether or not you were representing variability or uncertainty or probably some combination of the two, which be problematic in probabilistic risk assessments.

Any other points, though, that should be raised? Yes, Dr. Vu.

DR. VU: I think the recommendation is quite clear. But I do have a question for Dr. Leidy. One of the points that you raised as whether the Agency will consider inhalation of pms. And I guess we will ask them that question in Question 13. But in my mind, Office of Pesticide Program has proposed a inhalation pathway is a negligible route.

DR. LEIDY: And I read that.

DR. VU: And your opinion is we should explore further. That somewhat relates to Question 13, which is specific chromium VI. But I just wanted to look at that issue later. That's all. Thank you.

DR. LEIDY: Thank you.

DR. ROBERTS: Okay. I guess we can touch on that again in No. 13.

Any other comments on this particular question before we move on to the next? All right. Let's take the next question, please.

DR. EDWARDS: Question 12 has to do with combining multiple exposure scenarios into a comprehensive estimate of risk. Does the Panel have any recommendations for combining the four scenarios -- oral to wood, dermal with wood, oral with soil, dermal with soil -- combining these four such that a realistic aggregate of the exposure routes may be estimated?

DR. ROBERTS: Let's see. Dr. Wargo.

DR. WARGO: Yes. We took this as a question about aggregation. And we think that ought to be done. And we, also, think that we've talked a lot about the relative appropriateness of deterministic versus probabilistic methods, and I don't think we need to go through that again. I have some language that suggests that that is an important way to proceed.

On the issue of aggregate exposure, one issue that has not been brought up over the past day, but I think is important, is to

place these exposure in a much broader context of exposures that occur from other sources, including water, including food-based exposure. And this was done in the Gradient report in Table 5-1. So that we can see the relative contribution of exposure from arsenic in drinking water at different levels compared to the food-based exposures compared to the dislodgeable residues compared to the soil.

So from my perspective, if you're going to go the route of the developing a probabilistic model of kid's exposure to CCA from playscapes and decks, I would like to see the Agency go the next mile which would be to develop a model that would try to aggregate exposure across these different sources.

This has been one themes in my academic career is trying to encourage government to avoid narrowing the definition of the problem to such a limited scope that you miss the big picture, the big picture being total accumulation across all sources. And, obviously, that presents other kinds of data and analytical problems. But it only makes sense to make a choice about how to manage CCA in deck or southern pine outside the context of other exposure to arsenic or chromium or the mixture. I think it doesn't make much sense to me.

I just described my support for probabilistic modeling. I have a paragraph here that talks about how to deal with uncertain data. And I think that's a big issue, a big deal. The basic question in my mind is: When are the data good enough to include in the modeling effort, and what should be done until it is adequate because in many cases, it will not be. How should the Agency construct default assumptions?

And you've got a lot of good experience in doing that come out of the food safety arena under FQPA where you've been quite successful in thinking about how to aggregate exposure across food and water and consumer products, et cetera.

So I think as I look at your documents, especially your exposure document in Table 4 where you list all the parameters associated with these four exposure scenarios and you try to describe the level of certainty that you think is associated with each of these factors. I'll just read one of these.

"For child dermal contact with CCA-treated wood playground structures, medium to high uncertainty is associated with the parameters used." You've tried to characterize uncertainty for specific variables. I think this is really commendable, and I think I would push down that road. Be more

specific for each of the parameters, not only list the different sources of data, but your judgment about the quality of those data.

And in a 1999 panel that I participated in, this panel, we made recommendations for how to judgment data quality: replicability, whether or not it's primary data or secondary data.

There are a number that you actually have come back and cited in one of your documents. I don't have it in front of me right now. But I think that applying these criteria so that you have a very clear judgment that you go through routinely when you get a new data set in, that then gets catalogued, it just gives us a much more complete picture of whether or not we should put a lot of stock in those data sets. So I think that characterizing the uncertainty with great care is very important.

And also specifying what the default assumptions are going to be in the absence of credible data.

A couple of points about units of analysis. I think that there's been a lot of discussion about whether or not we should think of this problem as a problem of kids between the ages of one and six.

Again, the pesticide work in the food safety arena provides a road map for me where we started to break that down annually.

And we saw a lot of differences in food-intake patterns, water intake patterns year to year and actually within a year, when we have sufficient data.

So I think there is great value in collecting data at the individual level and collecting it for sample sizes that would permit this annualized approach.

I think that, also, I don't have a good understanding of how kids behave on playscapes. And I'm not certain that anybody else does and how that behavior varies across time and across regions of the country. And I think that everybody is in a position of thinking that this is important to know. Region and climate, I think, are likely to be very important predictors of at least playscape experience for outdoor recreational activities.

The school, the day care center, the residence, the town facility, these may all be the appropriate unit of analysis. I'm just finishing up a study of Connecticut school kids. And I've been monitoring their daily exposure to air pollutants using personal monitoring equipment and following them through their daily life. And it's really remarkable how much, how ignorant I was, about variability in exposure that occurs to a variety of different contaminants.

So that kind of individual tracking where you follow the kid from perhaps the school to the home to the town facility, may give you a very different image of how these exposures are accumulated across time at the individual level. And, also, how that might vary year to year.

I was struck by comments earlier that there likely is a lot of variability. And I think, Andrew, you mentioned with your own kids a difference between a toddler as opposed to a five-year-old. And the behavioral differences are likely to be quite significant there.

Also, I've done some risk analysis work on the area of biological diversity loss. And what I took from that work was the idea of hot spots where people that worry about loss of biological diversity, attempt to identify hot spots of biological diversity and the risk factors that are causing their rapid rates of destruction as a way of intervening.

I think that concept is maybe appropriate here, thinking about, you know, what are hot spots for kids? What factors might be overlapping that would put a kid at special risk? What facilities might be most contaminated? What behavioral patterns are likely to result in the highest exposure?

I was thinking not just about holding onto equipment, but I mentioned to several of you during the break, but what about the kid that's sliding down the pole or what about the kid that shuffles his feet across the deck that's getting splinters. There are certain behavioral patterns that may lead to higher levels of exposure.

What climatological conditions might result in the highest exposures and what age groups spend most time on these facilities.

I'll leave you with a comment which is that I hope that this kind of hot spot idea would lead to strategic attention that would provide the Agency with a clear imagine of how to reduce exposure in the shortest amount of time. You may be thinking of this as a problem of trying to set a regulation, which is what you referred to a few moment ago. You're anxious to set a regulation. But from my experience, the establishment of a regulation, a new regulation, doesn't often only result in exposure reduction.

So think carefully about a variety of interventions that might lead the Agency to affect real-time exposure reduction in the very near term rather than letting a regulatory decision just kind of trickle out there into the market place and hoping that it takes affect.

By this, I'm suggesting that public education and consumer

awareness can go a very long way in identifying where these exposures and risks are the highest.

And know that I probably stepped way out of the bounds here, but it's my own view here on how to really make a difference in a short period of time. So thank you.

DR. ROBERTS: Thank you. Dr. Leidy, do you have any comments to add?

DR. LEIDY: No, sir.

DR. ROBERTS: Okay. Thank you. Dr. Steinberg.

DR. STEINBERG: Wargo said it perfectly.

DR. ROBERTS: Okay. Dr. Ginsberg, will you guild the lily?

DR. GINSBERG: What?

DR. ROBERTS: Never mind.

DR. GINSBERG: The example that jumps to mind for me when getting into this question is the lead uptake biokinetic model experience and where the various media for exposure are compiled into a pharmacokinetic and exposure module and where one can get out of that the incremental increase in risk, well, in the case of the lead model, it's really an incremental increase in exposure and in terms of blood.

But from any particular environmental input, whether it be soil lead or house dust lead or drinking water lead, or airborne, it's all in there and it's fairly inclusive. It seems to me that something along those lines can be done for arsenic or at least headed in that direction so that one can understand where playscape risks, or exposures anyway, how they weigh in relative no everything else in terms of inorganic arsenic exposure.

And if we are near some subchronic or acute RFD for all the other backgrounds and this is the thing that pushes us over the top, that may be important to know. If this is really small increment relative to everything else, that may also be important to know, as well for cancer risk.

So I think you know the holistic aggregate exposure, not just for the four scenarios, dermal this and oral that, but also in terms of the multitude of potential contacts a child would have with pressure-treated wood structures, not just playscapes. And not just zero to six, but then we go on into adults.

So this becomes a lifetime of potential exposure to pressure-treated wood, whether it's having picnics on picnic tables that are uncoated or lounging on your deck if you're unaware of the issue. You're having your after, you know, you're evening drink

and a snack on it, your hands can be contaminated.

So there's a variety of scenarios that can be built in to make this a much more life-span holistic aggregate type of exposure than the isolate case scenario that we've been given to look at so far.

DR. ROBERTS: Thank you, Dr. Ginsberg. Dr. Solo-Gabriele.

DR. SOLO-GABRIELE: I just wanted to expand on the additional exposure routes that should also be included, not only the playground -- due to CCA not only playground as mentioned before, the issue of picnic tables is very important, not only from direct placing of food on picnic tables, but people tend to eat at a picnic table and they may have acidic-type foods, pickles and ketchup and put heir hands on the table and start eating again and that's a potential exposure route.

In addition to that, there is direct exposure from CCA in the disposal stream. For example, in a situation where CCA may be found in mulch and people may apply that mulch for landscaping purposes, indirect through potential contamination of the environment, eventually impacting soil concentrations as a whole or in drinking water.

I, also, wanted to mention that there's research to show that there are certain types of plants that uptake CCA and some of these plants are edible plants. I believe Dr. Stillwell could expand on that issue.

And also burning of wood is, also, another exposure route. Sometimes decks burn accidentally. Home owners may be at risk; fire fighters may be at risk. Sometimes wood is intentionally. Burned by individuals who are not aware that you shouldn't be burning CCA and use it for fire wood, for example. And then, also, there's the issue associated with potential exposures of ash associated with burned wood.

So there are a lot of other exposure routes in addition that a child may experience throughout their lifetime in addition to playground equipment that should also be taken into account when looking at the aggregate effects.

DR. ROBERTS: Dr. Styblo.

DR. STYBLO: I don't have a problem with combining scenarios as they're applied here, plus any other scenario that would include exposure to arsenic and chromium from CCA sources or CCA-related sources.

I'm not sure what is the value of combining this types of

sources with sources like food or water for one simple reason. To me, and I have explained it in here before, arsenic from CCA sources is different than arsenic -- we don't even know what it is. Let's say it's different arsenic from food and, certainly, from drinking water.

Would it be more informative if we combined, if we talk about combined exposures to inorganic arsenic or organic arsenicals or arsenobetines (ph) or arsenosugars as we know are present in all these sources. For toxicological reasons, it makes much more sense to me to talk about combined exposures to arsenic species with particle toxicological properties than to arsenic as total. Because arsenic as total doesn't mean anything from the toxicological point of view.

DR. ROBERTS: Dr. Mushak.

DR. MUSHAK: I would like to make two responses. One to Professor Ginsberg and one to Professor Styblo. I don't want to toss too much ice water on modeling arsenic. There are two studies underway to develop models. One from Diane Mensel's (ph) group at UC Irvine. And there's also one collaboratively between Marie Vahter and a group in Switzerland whose names now totally escape me.

The problem with these is that the way of these PBPK models work, they don't lend themselves to PRA very readily. It's almost like you develop a classic mix of point estimates. And if you started doing PRAs for every step in a PBPK model, my gosh, it would just be overwhelming.

Even in the lead model with its inputs, outputs, and biokinetic components, about the only accommodation you get for a variability is on the output end with the geometric standard deviation.

Barbara Beck's folks at Gradient have been trying to build in PRA for the input side. But I don't know that you could combine that too much with the biokinetic side, even for that relatively simple model. So I think we're a long way from PBPK modeling of total exposure to arsenic.

With regard to speciation, I don't notice you get out of the woods, or the wood, the real problem with this which is that inorganic arsenic is probably going to be speciating in the same way as it comes off the wood surface as say inorganic arsenic in drinking water.

Dr. Styblo and I were discussion briefly before about what are some minor components in CCA that may serve as useful

tracers that are unique to CCA as a source and dislodgeable residues that may not be present in other intake sources. And I guess this would be a question to the chemists and engineers from the wood industry who are here.

What's the profile like with minor metal components in CCA-treated wood? We know that you're probably not using analytical-grade reagents by ACS definition. You're probably using particle grade or technical grade. So there are a whole bunch of minor tracers that may be in this and that may be useful to use to sort of tracer tag in terms of a biokinetic corollary to what Ed Calabrese does with intake tracers.

DR. ROBERTS: Dr. Clewell.

DR. CLEWELL: I'm not exactly sure I understood what Dr. Mushak was saying about PBPK modeling, but it sounded negative.

We've done probabilistic modeling with methylmercury and published that. And the arsenic model, I'm actually working with Sibingman (ph) and Marie Vahter on the extension of that arsenic model. I don't see any reason why it can't be used in probabilistic assessment. It's not the like the lead models, a biokinetic model. It's not physiologically based. That's different.

So that wasn't really what I wanted to talk about. It's the

aggregation of risk, a caution that I feel related to what we ran into with the noncancer endpoint. But for the cancer endpoint, arsenic is kind of an unusual burden. There's no reason right now not to believe that we are all at greater than one and a thousand risk for lung and bladder cancer from the inorganic arsenic that we that we eat.

At the estimates 10 micrograms per day. I've been told that the FDA recently estimates 25 micrograms per day inorganic arsenic in food. And so no matter how low they set the MCL, we're going to be at greater, given the new risk numbers, we're going to be at greater than one in a thousand risk of cancer strictly from the arsenic we eat. So then you add in the drinking water.

So I like the idea of comparing the arsenic exposures and risks from the CCA, all the various CCA exposures, with that from the water and the food. But I wouldn't suggest combining those.

DR. ROBERTS: Other comments or other viewpoints? So we seem to have some differing opinions about the extent to which -- I think everyone would agree about the value of comparing. We seem to have some different viewpoints about to extent to which exposure from different sources, not necessarily different routes of exposure, but different sources should be aggregated.

DR. SMITH: I guess just to get on the record here I guess, I would have some concerns about expanding the aggregate to thing beyond CCA wood just because of the current regulatory focus and needs. And I think that's going to be a difficult task as it is to get that right. So I would like to see them focus their efforts, at least initially, on that. If the Agency wants them to take an aggregate analysis of all arsenic exposure, I suppose that could be useful.

The other thing is, again, I just want to emphasize I really do want you focus on the aggregate exposure from all CCA wood uses. And it's probably always worthless, but I'll give you just my little anecdotal experience, you know, being up in rural Maine.

You know it's always astounds me of how prevalent this wood use is. You're aware of that as well. Where I live we have a deck that's pressure-treated and we have an wood entry way that's pressure-treated wood. So every day when we go out to school and my son's going into kindergarten and he's not particularly happy about this.

So he leaves the house, the thumb is already in the mouth until he gets to the stairway. He puts his hand on the stairway. He goes down and gets into the car. And the first thing he does is the thumb goes back into his mouth. We drive to there. After his

school, he goes to his day care. Well, his day care has a pressure-treated wood entry way. So now he's going to have some exposure going in and out of the day care.

And up until this year at his school, there used to be a very large pressure-treated wood playscape. This year, we just switched to the metal enamel type. Until this year, that was the same.

And I can talk about how when we ride our bike down the street and we visit people, you know, it's the same scenario. This is just a very, very common wood in certain areas of the country. So I think it's going to be a real challenge to you in doing a cumulative exposure to think of these. It may be very different in different graphical regions of the country.

But I really do think if we're going to look at the exposure from this, just focusing on playscapes is not the issue. And I think 130 days may make sense when you think of the municipal playground. But when you start to think about all what's going on around the home, it's just far, far more frequent, I would think.

DR. ROBERTS: Dr. Vu, was there some clarification you wanted to offer us on something?

DR. VU: Thank you, Dr. Roberts.

I'm hearing two different recommendations. Dr. Wargo was talking about total aggregate risk from all sources for arsenic or chromium which is a different kind approach which is not with the focus right now within the Office of Pesticide Program which we really worry about risk associated with CCA-treated wood.

And I'm hearing Dr. Steinberg and some of you on this side have recommended looking at the whole life cycle of the CCA-treated wood from the different uses and how the human populations are exposed to it. Not just children alone, but as we all age and how we get the whole life stages.

Certainly that is a very laudable goal. And certainly we know that we don't have all the data to do that. And as Dr. Edwards had said at the outset, that we're looking at different exposure scenarios, residential, and others, and we will try to combine as much as we could. And that was basically the question. With regard to playground should we at least combine these four scenarios. It doesn't mean that we're not going consider other scenarios.

But really to do the kind of think you were just talking about requires a whole lot more data as well. So even though it's ideal to have all that information.

So I just want to get some sense from you that what is the recommendation you have with regard to this question and then the broader what you think is realistic given the difficulty even just to do the playground thing as we deliberate in the last three days and let alone look at the whole other scenario. Thank you.

DR. ROBERTS: Dr. Ginsberg, I think wants to take a shot at it.

DR. GINSBERG: The one concern that may come is about double counting, the potential for double counting when you're saying this there's a child playing for an hour on a playscape and has all this opportunity for dislodgeable exposure. And then also is going to be exposed to 100 milligrams of soil ingestion a day beneath the playscape.

So I mean it just seems that there's both media that will be contacted, how to break that out. It may not be so simple as 100 milligrams, you know, the full maximal daily dose to that soil and also for the full hour of contact to the wood.

That's my only certain is if there's any double counting going on there. But otherwise, dermal and soil -- I mean, dermal exposure and ingestion exposure, I think, go hand in hand literally,.

DR. ROBERTS: Dr. Steinberg.

DR. STEINBERG: What I think we had in discussion with my colleagues, Dr. Leidy and Dr. Wargo, I think what we wanted to make sure was there was not going to be an aggregate of all the scenarios and employ a deterministic model as it relates to how you were going to do this. The EPA over the last few years has worked hard in developing the specific behavior types of patterns, the EFH manual and a bunch of other things. We felt that that was a very good forward step.

The probabilistic model includes that fluidity of these different varieties of exposures and allows you to add on further exposures or further risks or further scenarios that will occur. So I think that's the point. I don't think people wanted to make this a overzealous burden, but rather employing a probabilistic model meant that you would evolve to a better model as time went on. But you would clearly have a good active model to begin with.

DR. ROBERTS: Other comments? Dr. Smith, Dr. Wargo.

DR. SMITH: I guess to respond directly to your question. I support combining the exposure scenarios. I think what I was trying to emphasize is I would have concern in your analysis solely of playscapes you reach some decision or some conclusion

that was based solely on that. If your decision process is going to be yes, we're going to do this. But before you make any decision about the future of CCA wood or what you think of it, et cetera, it's going to look at these additional exposures as well. Is that correct?

DR. VU: Yes.

DR. ROBERTS: Dr. Wargo.

DR. WARGO: I take the advice well that a comparison of different sources of exposure may be the first step and that could lead to an expanded modeling effort. I think that that sounds pretty reasonable to me.

The scenario that I had in mind was that the high-end exposure in Connecticut where we don't have much of an arsenic problem in ground water, may be a very different situation than a high-end exposure from CCA, say, in the Southwest, where they do have a ground water problem. And it's the patchiness of the problem that I think has to be given more attention.

And, again, how these high-end exposures; one may not regionally defined, another regionally and seasonally defined, and another regionally seasonally and behaviorally defined. How these risk factors might be overlapping one another. My own view

of this after looking at it for just past the few weeks, but reflecting on my past work in pesticides, is that this distribution is likely to be very heavy skewed. What I do hope is that the modeling effort and the analyses that you prepared can shine the flashlight on those kids that are really experiencing the highest levels of exposure.

DR. ROBERTS: Thank you. Is there anything else to add? Have we reached either convergence or exhaustion on this particular question? Dr. Vu, is it clearer now where the Panel is on this?

DR. VU: Yes, thank you.

DR. ROBERTS: Let's do one more and take a short break. Let's go onto 13. And then we'll take a short break. Could you read No. 13, please.

MS. AVIADO: Certainly. Number 13 deals with the inhalation exposure potential for wood and soil media. Can the Panel comment on whether OPP should conduct a child playground inhalation exposure assessment, taking into consideration the hazard profile for chromium VI as an irritant to mucus membranes. If so, can the Panel comment on whether the endpoint described above is appropriate for assessing the risk to children from such an

exposure. The endpoint, of course, you recall was discussed in the hazard presentations.

DR. ROBERTS: Thank you. I have down on my notes that Dr. Gordon would like to jump in on this first. Let me ask him to do so. But he needs a microphone

DR. GORDON: Pretty tricky getting the computer at the right distance so I can see it without bifocals.

In answering this question, I feel there is no data on ambient metal concentrations in the vicinity of a CCA wood play structure. And the soil in the immediate vicinity of a play structure. And I use play structure because everybody has been saying "playscape," and I think that's the name of a company. I think they make only cedar products. They probably don't want us saying playscapes.

But inhalable particles can be resuspended and reentrained in the air, and, thus, in the notes from EPA, where it said the volatility of chromium and arsenic is irrelevant. I don't think volatility matters here. It's the resuspension of the dirt in that scenario.

Most mechanically generated particles are very large and thus inhalable and not respirable as mentioned in the document. Inhalable size particles are of concern and most particular to the

nasal effects of chromium.

There is a need for calculations for the range of background values. Of course, this can be added on to the studies EPA and Consumer Product Safety Commission. And it's important to compare these values to ambient exposures for chromium. The same thing we're going through in the last question. How do we compare it to water or oral ingestion of food.

And considering a 15 kilogram child and a one- to three-hour exposure. Now the assumption of a 100 percent hexavalent chromium, I think, is an overestimate of the proportion. I said that earlier. Especially since the wood is probably 90-plus percent trivalent. But there's very sparse published data on hexavalent versus trivalent. And except for what we heard yesterday, none for soil. And such a data set needs to be developed.

I'm in favor of developing an inhalation route of exposure. But against that need on the other hand is an examining the playground exposure to chromium. In arsenic workers that are exposed to much higher OEL for trivalent chromium, far, far greater than eight-hour exposure level.

The one study that I know of is the one that my master student did a few years ago. And the person who sanded, they were

make playground equipment, the person who did the sanding was literally covered probably your 3 milligrams per centimeter squared there, literally covered with sawdust. And he was not over the chromium standard on a respirable, far above for arsenic, by the way.

And in there they talked about the NOAEL for the nasal effects 2.4 times 10 to the minus 4 milligrams per cubic meter. It comes out to 240 nanograms per cubic meter. That's probably at least one if not a couple magnitude greater than the background level of at least arsenic probably chromium of maybe magnitude than in an urban environment unless there was particular fuel source like coal that happened to have a lot of chromium arsenic in there.

And when you calculate that out, given even the 240 nanograms per cubic meter, I guess it's borderline. It's going to be way down there. But the total microgram loading might be a few micrograms per day, micrograms per kilogram days.

So when I did my quick calculation it sort of said maybe there is no need for an inhalation. I can't as an inhalation toxicologist say that without knowing what the levels are in the immediate vicinity of a playground structure.

DR. ROBERTS: Okay, Dr. Lees.

DR. LEES: I'd like to directly comment really on the nasal irritation. And this comes from my own occupational studies in which, you know, chromium manufacturing facility there's a very, very high prevalence of nasal irritation and septum deviation. I think it's on the order of 60 percent of the population at one point. But we didn't find any relationship between air concentrations and the symptoms.

And the suggestion is made, well, by others, let's say. And it maybe particularly a propros to the child environment that it's not the inhalation but it's the digital insertion of hexavalent chromium into the nose, picking your nose. These behavioral things might have a greater effect here.

And so I'm not really certain whether the air has anything to do it with at all. And maybe some -- all I know is there are no studies to this effect. It's an observation here.

MS. AVIADO: Might I clarify, if possible?

DR. ROBERTS: Sure.

MS. AVIADO: Because the nature of the question, we are truly concerned with both the wood residue and the soil residue. And the concern on the volatility was based on really thinking in

terms of the wood surface residue, the particulate, the airborne of concern to us was during the contact with the soil.

And the point you've raised is truly important in terms of what happens to any soil particles that enter the nose or enter the mouth. And this is our issue: Which is if there is soil in the nose, in the mouth, can we assume it makes up a portion of the ingested dose to the GI tract? Does it need to be considered separately as inhalation exposure? Or would we assume that it makes up part of the oral dose?

That's truly where we're going. We feel confident on the lack of respirable because of lack of volatility on wood surface. And also the reassurance to both of you, certainly, that in our full comprehensive assessment, we'll do occupational inhalation. We'll also be doing residential adult inhalation scenarios for sawing and fabricating any picnic tables and things such as that. Thank you.

DR. GORDON: Given the NOAEL, I'd say, yes, maybe inhalation exposure routes doesn't need to be considered. I have no idea if a playground resuspended, residue resuspended soil, levels are higher and lower than that NOAEL. And so the thing I didn't say was I think that should be an added area or personal

samplers to the EPA's CSPC study.

DR. ROBERTS: It's becoming an expensive study. Dr. Shi.

DR. SHI: I have just several comments. And number one, in regarding the issue is the question we're asked many, many times. And what's the ratio between chromium III and chromium VI. Because inhalation as powder of chromium VI is a bigger problem, not the oral intake. And in the occupational study, we are concerned more on the inhalation of chromium VI. And this is the first. And the question remains to be answered.

And second, as Dr. Gordon just mentioned, there's no available data concerning how much chromium available in the air, for example, per cubic in feet. It could be in meter. It's just not available.

And even as though the inhalation is a very important issue and the body is a much more sensitive to the inhalation than oral intake. But it's not expected. There's not very much chromium-contained dust in the air unless they put it their by nose by accident or something like that.

In my opinion, there may not be a major concern unless and really go to the playground to measure the airborne particles that are respirable chromium content. So without all the data right

now, it's just a piece under available data. I feel the inhalation toxicity or carcinogenicity may be not be of major concern at this moment.

DR. ROBERTS: Ginsberg.

DR. GINSBERG: I would tend to second that last opinion.

I just don't think of deck surfaces themselves as being that dusty and dirty given all the opportunities for the weather to wash away residues so that it's not going to be like an attic where you've got a lot of dust built up. And the material underneath the deck will oftentimes be sand which I would expect, given the particular size, to lead to large inhalation opportunities.

And for the other materials, the tire chips or the wood chips, the one concern I would have in our little minigroup that has Questions 14 and 15, talked about this last night.

The one concern I might have is if kids are intimately playing in construction debris, CCA-wood chips that are breaking down and are forming a dust and they're throwing those around and there may be some inhalation to fairly concentrated, very probably brief. Because, again, the particular size is going to be big and it will fall out. But if kids are crawling around in it, they might be down in a zone where you might get some dust exposure.

So that's the one scenario where I would be a little concerned. But again if 90 percent of it or so is fixed as chromium III, I'm not sure the Agency should spend a whole lot of time on this especially if it's only construction debris type of concern. But that's just my opinion.

DR. ROBERTS: So am I hearing the answer is no.

DR. SHI: I feel the answer is no. In particular, if you consider this is outdoor. This is not indoor. And the air flow is not that much in chromium-containing particular in the air. It's purely, I would say, most of the kids is outdoor activity.

DR. ROBERTS: Dr. Solo-Gabriele.

DR. SOLO-GABRIELE: As far as the inhalation issue, I think it would depend a lot on the buffering material that is placed underneath the playscape. If you have pea gravel or sand, the probability of inhalation exposure, I believe, would be small. Where as if you don't have a buffering material, which is typical of many residential playgrounds it's on plain dirt. Or if you have mulch, in which case, the mulch can be contaminated from the playscape itself. Or in some cases, it may have some CCA-treated wood in it.

So in the case of mulch in the nonbuffered playground, those

particles -- mulch has a tendency to break up. Dirt, also, has fine particles associated with it that can be easily, depending on the activity level underneath the deck, it can be up brought up into the air and inhaled.

So I think it would depend a lot on the characteristics of the buffer material that's located below the deck.

DR. ROBERTS: Dr. Wargo.

DR. WARGO: My impression is that this is not likely to be a significant source of exposure compared to the other routes.

I think the two scenarios mentioned, the wood chips, that's a possibility. The only other one that I could conceive of is a very low diameter particulate matter in sand where, you know, kids were scuffing that up, you can see a little cloud. But I'm not overly concerned about it.

DR. ROBERTS: Dr. Styblo and then Dr. Adgate.

DR. STYBLO: I sort of hoped I would be the last one because as I said, I'm not an expert on chromium and I'm not going to talk about chromium.

Are we supposed to give our inputs on possible inhalation of arsenic species?

DR. ROBERTS: Where an inhalation for arsenic needs to be

given?

DR. STYBLO: Yeah. Because the question is about how inhalation. For some reason, you're asking about chromium only.

DR. ROBERTS: Yeah, it is. Tell you what. Let's put that at end category because there's a couple of them. Dr. Vu, unless you want it talked about right now.

DR. VU: I think there are two issues. First of all, I think the issues you all discuss is we probably need some more data to really find out whether inhalation pathway from soil. We know it's low volatility from the soil contaminated with arsenic or chromium and that's the issue. And I think probably we can collect more information and confirm that.

I hear the consensus from the panel is that right now we don't think it's a significant exposure, but let's get some information to confirm that.

The second issue that we raises, then, if indeed there some substantial exposure, then do we worry about what kind of endpoint was concerned? Now, the reason why we asked this question because chromium VI, when we talked about the dermal exposure, we said it is an irritant for the skin and also causes skin sensitivity.

So in the scenario we talked about kids playing in dirt. There's no inhalation pathway. It's just dirt and (inaudible) to mouth. And, of course, it could irritate the mucus membranes.

So I think that's the question. There isn't hazard endpoint here for chromium. We're not talking about arsenic yet. But this is two separate issues and somehow we kind of mesh it into one.

DR. ROBERTS: Okay. Then with that clarification, Dr. Gordon.

DR. GORDON: Maybe because I'm the only inhalation guy here. There is no data. I don't see. A lot of people said no and just off the top of their head, mulch, this, there's not that much and that's completely meaningless to me without the measurements.

You talk about the buffering material. Where I'm from in New York, I don't see -- it's sand. It's dirt. We don't have buffering material that I've seen in most playgrounds I've been at and I've got little kids. So it does make sense to me. I keep thinking of the little Peanuts character and the cloud of dust. And that's more appropriate.

And, also, I'm wondering when you think about lead, do you only go by hand to mouth; or is it, also, the lead that's resuspended in the homes because I thought inhalation did play a part there. I

don't know.

DR. ROBERTS: Dr. Adgate.

DR. ADGATE: I can tell you from you my knowledge of particles, that the smallest particle you can create by crushing and grinding is on the order of one to three microns. And those were the smallest ones which you can create a physical process. And those are the ones that you're going to inhale and that get deep in your lung and deposit are going to be on that order. But a lot of the bigger particles that I think are going be created and kick up like in the pigpen effect, are things that are going to get filtered out much higher or are going drop out very quickly.

DR. GORDON: But where do those filtered particles go?

DR. ADGATE: In your nose. You're absolutely right and they you swallow them and it's an oral exposure. So then it becomes a gastrointestinal exposure and not an inhalation exposure.

DR. GORDON: I agree with Dr. Styblo about why aren't we including arsenic in this?

DR. ROBERTS: We can and we will when we get there. Dr. Ginsberg.

DR. GINSBERG: There have been attempts to evaluate the

amount of -- there's models, like AP42, that simulate how much dust there can be from loading and dumping into trucks and heavy equipment driving on dirt roads and the dust inhalation you can get downwind from all of that if you're at the fence line for this activity. And, classically, the amount material going in is usually dominated by the soil ingestion assumptions rather than these somewhat transient exposures vie inhalation just based upon bulk flow, how much inhalation flow you can get for these particles.

And in this scenario where we don't have these massive amounts of dirt being moved around and big clouds of stuff forming, I would just think that the reason you would want to focus on inhalation might be because we've got something unique by inhalation that wouldn't be occurring by oral. And that is chromium VI toxicity which would be more severe if it's inhaled than if it's ingested.

So I think if we're talking about something that's going to be inhaled only to be ingested, then we're back into comparing it to what's the bulk flow into the body via ingestion. And I think that the inhalation pathway would pale compared to what we're modeling for ingestion.

I don't know that we have to spend too much -- my opinion is

we don't have to spend too much time on that part of it. But, again, I think it is relevant to be concerned about chromium VI inhalation. And are there subscenarios here where that can be much. And, again, I don't think it's a lot. But as Dr. Vu said, it would be worth trying to get a little more data on it.

DR. ROBERTS: I think we're sort of not moving much past Dr. Vu's summary a minute ago which her impression of what we were saying is we don't think there's a problem, but it would be worth the exercise of demonstrating that by conducting an assessment. And I guess her question back to us is: The most appropriate endpoint in that assessment, would that be nasal mucus irritation. And is the answer yes or do we have an alternative endpoint that we would want to suggest for inhalation from chromium VI when they do this analysis.

Dr. Shi.

DR. SHI: And the answer, the my opinion, is yes. I agree with her.

DR. ROBERTS: Anyone else like to second that or venture a different opinion about. Dr. Ginsberg.

DR. GINSBERG: Well, as long it's not conceived of as on ongoing chronic exposure and we're not talking about cancer, then

I would say yes.

DR. ROBERTS: Right. I think the assessment at this point is focused on noncancer. So would that be the appropriate noncancer endpoint for inhalation?

DR. GINSBERG: Yes, I would agree.

DR. ROBERTS: Right?

DR. VU: Yes.

DR. ROBERTS: That's it. So Dr. Vu is our input clear than I guess now on this?

DR. VU: Yes. We can take a break. Thank you.

DR. ROBERTS: Okay. Well, that's right. Let's take like a ten minute stretch, and then we'll reconvene and finish up.

(Brief break.)

DR. ROBERTS: If the panel will convene. We have two questions remaining that are posed to us by the Agency. We also have I think at least a couple of other questions we're going to have to tackle at the end. I think we're close enough to having everybody here that we can go ahead and start.

Will you go ahead and read for us, please, Question 14.

MS. AVIADO: Question 14 has to deal with the consideration of the buffering materials as a source of exposure.

Data on the effectiveness of reducing exposure by using the buffering materials are limited. And we ask if the Panel has recommendations as to whether additional studies to obtain this information are warranted. Does the panel have suggestions on how OPP can best child exposures attributed to contact with the CCA-contaminated buffering materials.

DR. ROBERTS: Dr. Ginsberg, I believe you have the lead on this one.

DR. GINSBERG: I think the issue should be divided along two different thought processes. One is that buffer materials being the recipient of dislodgeable residues from a neighboring wood structure. So I'd call that just to reference that I'd call those buffers versus buffer materials that have CCA wood mixed in with them, which I would call source material buffers because they are their own source of contaminate. So I'll just tackle the first that I mentioned first, the recipient buffers.

Oh, and in both areas I think some data generation would be helpful to understand, really, the risk implications.

But the general principles, on first principles, the way I think of these recipient buffers would be that that first assumption I'd make is that most of the CCA that would be dislodging and

leaching off of a play structure and getting down to the material would stay on the outside and not necessarily absorb or penetrate into or become immobilize but would form a residue, just like on the wood structure that it's coming from, again, form a dislodgeable residue, so to speak, on the tire chip or the wood chip so that that would become now an exposure medium for a child just like the wood surface would be. And that the concentration, we don't have concentration date; and, of course, it would useful to get that data. As we go out and do this field study, another point of data generation.

But short of that, my first impulse is to say that it's not going to be any higher than what we're seeing on wood surfaces. Why would this be a medium that would accumulate CCA that's dislodged off of a neighboring structure, unless again we're envisioning that it somehow absorbing onto and not being released on from it and so it can accumulate. It's sponging it up. I don't see that as a mechanism. But who knows. But if it is sponging it up, then would it release it to a child's hand.

So I think it may be reasonably conservative to assume that the concentration that's available and dislodgeable on a wood chip is similar to the concentrations that we've been seeing that's been

hand wiped off or swiped off of a deck. And the other reason I say that is because I think there'll be an equilibrium set up between the washing onto these materials and the washing off to these materials by the rain action that's happening, bringing it on but also talking it off. So I think we can think of those concentrations in those terms as what we're seeing on the deck may be similar to what's on these tire chips or wood chips.

And then I thought of an exposure scenario. How do we start developing exposure scenarios for these recipient buffers. And I thought of two ways two scenarios. One is actual putting the whole chip in the mouth, which would perhaps involved complete removal of the entire surface area of dislodgeable material in the mouth if you want to make a conservative assumption that it's in the mouth long enough and then spit out. I'm not assuming the child's going to eat this thing. But he might want to find out what it feels like to have the -- what's the mouth feel of a tire. You know, I don't think a child is going to do this a lot unless it's a pica child. But I would think any child might do it a couple of times.

So there's that potential scenario. And it doesn't strike me as being a huge extra risk in the equation. I think it should be

thought about. I think some calculations around this. But I did a little mock-up of this where and conceived of a one-inch square wood chip by a half-inch think thick, so the total surface area of this little chip is 26 centimeters squared. If it's one inch by one inch by half inch, it's 26 centimeters squared. And that's roughly the three fingers we're talking about, 20 centimeters squared. That's roughly the same.

And if the concentration on the three fingers, which is getting it from the wood surface that we've talked about, is roughly the same of the concentration of the recipient buffer, but we're saying that the fingers are going into the mouth nine times an hour. And this probably isn't going in the mouth nine times an hour. I'm not seeing that that scenario as being real high compared to what we're already envisioning, EPA's assumptions at least, for hand-to-mouth activity. So that's just one person's way to think about how important that pathway might be.

Again, there's a lot of assumptions I've just made, and I think it would be very useful to go out and generate data on what is the amount sort of at equilibrium of these chips in terms of what's available and what's dislodgeable. And I think that could probably be done by dropping a certain number of them into a .1 normal acid

bath and just then rotovaping it down and measuring what's available compared to the surface area of the materials that were in that bath and to find out what the concentration is on the surface. That's one possible scenario, which, again, I don't personally think it is going to add a lot of risk to the scenario given we're already envisioning children being these decks for an hour with 9.5 hand-to-mouth contacts, 20 centimeter squared, going there the mouth.

However, another scenario what might be rather than the whole chip going in the mouth could be the dislodgeable residue going from the wood chip onto the hand and then the hand to mouth activity. And here I think it would be useful to know, given the high surface area of these wood chips and maybe children's propensity to play with them and really interact with them, it may be more than a child's propensity to intimately engage with the wood surfaces with a playscape play structure that may be a greater wood-to-hand transfer factor in this case than from the playscape.

I don't know. If you assume that it's the same, then I don't see any reason why that exposure pathway would be any different than what you're already proposing to model for the wood

structure. But if there's a higher transfer efficiency, once again, it might be something you'd want to find out about in a playscape study involving children. Then that could become a special risk pathway if the transfer factor is higher.

So the two cases where this could be a special pathway, I would think, in terms of these recipient buffers, is if the dislodgeable residue on the surface is higher than on the parent wood, which I wouldn't think it would be. But until you test it, you don't know. And then if the hand-transfer factor is higher when a kid is playing with when the chip is playing with and throwing them around and handling them these high-surface materials relative to their swiping of a deck. If that's higher, that could become a special exposure pathway.

Again, I don't think either one will become those exposure special pathways, but I think that should be tested and ruled out.

So, again, this is just one person's thoughts on all this. I didn't necessarily get consensus amongst my peers, the three of us that tackled this.

But then the other side of the equation is if we have construction debris. So it's actually a source of new contamination because the CCA, wood is being mulched into this.

There, I think, that there is the potential for significant extracontamination of the environment, of the child's hand.

One is that there could be breakdown of the mulch material into a dust, not just the leaching effect going on, but a wholesale availability of wood dust containing fairly high levels of CCA that would be different, physically different, than just leaching.

So I think that pathway should be ruled -- I would hope that that pathway should be not even necessary to do a risk assessment on because I think that it is a no-brainer that, number one, the industry doesn't condone it's use. I don't think regulator bodies would condone that kind of a use for CCA wood, and that while it may happen, you know, while this may be an unfortunate reality, I don't know that -- you know, there's this sort of like no registration issue around this.

And my recommendation around that, and I'll turn it over to Helena more on this topic. My recommendation on this would be exclude to just try to exclude this pathway as much as possible because there's no benefit to it.

DR. ROBERTS: Dr. Aviado, would you like to clarify or respond?

MS. AVIADO: Just as a point of clarification. Our

consideration for the Panel is, also, the other types of building materials. So if you can please keep in mind to help us the affinity a child may have for playing with the pea gravel or the shredded tires.

I think we heard from a public commentor a great affinity toward the actual shredded-tire scenario. And even though the amount of leachate may be similar soil buffering material, the child's activity or behaviors may be different for contact with the pea gravel as opposed to a wood chip only sort of consideration. Thank you.

DR. ROBERTS: Dr. Ginsberg, did you want to say anything in response to that?

DR. GINSBERG: Yeah. The two scenarios that I portrayed, one with the actual mouthing of the material, I think that would cut across from wood chips to tire chips to pea gravels and washing off of that dislodgeable residue into to the mouth I think would cut across whatever the medium is.

The medium I haven't talked about is sand. And I would think that it would be useful to get some sand data especially if there's playscapes that we know have a lot of dislodgeable residues on the wood just to see what that relationship is. I don't recall in

the data sets that we've seen if there's a lot of sand data underneath playscapes. If there isn't, then that would be useful to look at that.

And then the only other point that I would note is that the Alachewa (ph) data showing that the tire chip concentrations were similar on the tire chips in terms of ppm is about 50 to 70 ppm on tire chips that were near wood structures. And it was very similar in the soil that was underneath the tire chips. So that it seems like a similar kind of exposure amount. At least the amount of the environment is similar.

Now, of course, a child may have more intimate contact with a tire chip than with soil in terms of handling it and being able to dislodge material off of it.

So those are my initial thoughts.

DR. ROBERTS: Thank you, Dr. Ginsberg. Dr. Smith.

DR. SMITH: I'll defer to Dr. Solo-Gabriele.

DR. ROBERTS: Dr. Solo-Gabriele.

DR. SOLO-GABRIELE: I just wanted to reiterate some of the points that were brought up before. I wanted to begin by first emphasizing that the amount of data that is available is very, very limited.

The data that we had available to evaluate was that Alachua

County data, included the Alachua County data, which is the only that sampled specifically buffering material underneath playgrounds. And that was a very limited number of samples from a very localized area. And what we learned from the study is that the buffering material is contaminated to a similar degree as the soil. But, again, this is one location and a limited number of samples.

Also there's the data looking at the mulch issue, looking at mulch from construction demolition, recycling facilities, which was emphasized yesterday. I don't think I need to repeat that. It's fairly obvious, at least in Florida, that CCA-treated wood is found in mulch made from construction demolition debris.

What I wanted to add to that was, in Florida, we've been getting a lot of attention with respect to the mulch issue. It's been in the newspaper; it's been on television. And as a consequence, I've been getting many phone calls from people, home owners, that are very concerned about their mulch. So they've been sending me samples. I've gotten samples from local playgrounds, people's gardens in Florida. And I did get one sample from Arizona which I wanted to emphasize.

And in some cases, the samples that I've received, the mulch

from the garden, in particular, I remember had CCA in it.

The one sample from Arizona that I wanted to emphasize was a father that called me. In Arizona he explained to me that using mulch for playground equipment for buffering on playground equipment is very common because of the climate and the wood doesn't get very hot there.. And he explained that he bought this mulch called "place safe," and it's marketed in Arizona specifically for use on playground equipment. And he was very concerned because the mother, the wife, found an end tag inside the mound of mulch that was delivered to his house.

And, fortunately, this end tag came from California. And the type of labeling they have on this end tag is very different. It was different. It's different than what I was used to seeing in Florida where it is specifically stated that this wood contains a hazardous substance, arsenic. And it was that wording that alarmed this particular father.

And so he did a web search and found our name. And we accepted some of that mulch, and we did a quick analysis on it. And, in fact, it did have CCA. We applied a chemical stain to it, and it was greater than 5 percent.

The important thing about this particular sample, is that this

mulch was marketed specifically for use at playgrounds. It was called "play safe mulch." And I just wanted to emphasize that. And it was the only sample that I received from out of state.

I also wanted to emphasize the types of buffer materials and the type of buffer material will greatly impact the exposure of the child, whether or not you have sand, pea gravel, tire chips. For example, I think the affinity for tire chips would be higher because you can dig into with and you won't scratch your hands. Where if you try to dig into pea gravel, you know, you have a tendency to scratch yourself. And there's not as desirable to do. So there will be a natural tendency not to dig into pea gravel versus tire chips.

Mulch is one of those materials that you can dig into which may have a high affinity as well.

With respect to some of these buffer materials which I mentioned earlier, the mulch, when the particles, the mulch material is broken up, there may be a potential inhalation route. Same situation for playgrounds where you have no buffer material just direct dirt. And then there's the special case where the mulch may be contaminated with CCA where you may have an added problem associated with direct mouthing of CCA-treated wood.

As far as the recommendations are concerned, I recommend

that we need more studies, given the limited amount of data available, to characterize types of buffer materials used underneath playgrounds. And it's my understanding that the types would be dependent on the region in the country.

In Miami, I'm used to seeing sand underneath the playscapes, but in other areas it would be different. And we need to understand what is the fraction of playscapes that have different types of buffer materials so we can get a better handle on this.

We need to collect and analyze samples of buffer materials to how much contamination may be on them. And, also, the issue of infinity needs to be evaluated as mentioned before.

I, also, thought, given the special problem associated with mulch, that we also need to quantify the fraction of playgrounds that use mulch as buffering materials. We need to conduct the study throughout the United States. I, also, think it's important to warn consumers about the potential for mulch contamination, not only for playgrounds but generally, and emphasize that mulch needs to be carefully examined and evaluated before it's used on playgrounds.

DR. ROBERTS: Dr. Smith, did you have anything to add?

DR. SMITH: No, I have nothing to add.

DR. ROBERTS: Other comments from other members of the panel. Dr. Chou.

DR. CHOU: I want to add to the concern of the buffering material. Because to children -- and to adults, it is a function of a buffering. But to children that is actually another attraction. We talk a little bit about children want to dig into the buffering material.

And it's known that children are attracted to anything that is a different color, a different texture, different shape, anything you can pick up, line up, make a pattern. And that's a well-known children's behavior. So the point is it does create another attraction. Children look at it differently than we do.

DR. ROBERTS: Thank. And I might just say, we saw, I think, from Dr. Townsend's presentation, that we can probably get a pretty good idea right now kind of what the soil levels we're going to find around these kinds of structures. And I think it's certainly worthwhile to refine those estimates. I think we have a pretty good feel for what kinds of concentrations we're going to have there.

But we have very little data on buffering materials as Dr. Solo-Gabriele said. And I think it's hard at this point to know

whether or not it's a big problem or a small problem or not, although there's certainly enough, I think, to suggest that we need to gather some more information to see how often this occurs, what kinds of buffering materials are used, in effect we see a lot of arsenic in these kinds of things or chromium.

If we find that, then, of course, you really are in virgin territory in terms of doing exposure assessments on buffering material. I don't know of anything out there that you can grab right away. Dr. Ginsberg has made some suggestions about kinds of thought processes you could go through.

But in terms of data and in terms of what kids actual -- documented evidence other than anecdotal information about what kids actually do with this and how they come into contact with it. I think this is going to be tough because I don't think you have much to work with at all there. And if you find it a lot and you find it in significant concentrations, I think you're going to be compelled to begin to get some information about how to assess that.

Dr. Smith.

DR. SMITH: If I could just add one of the benefits therefore of a study that's actually going to look at kids and get hand wipes

of kids and possibly also get internal biomarkers, is that we capture the entire experience.

DR. ROBERTS: Are there any comments on this question? Dr. Morry.

DR. MORRY: David Morry, California.

The first question there seems to be asking to suggest studies that would help us to compare exposures caused by buffers versus exposures caused by not having a buffer there. And it seems to me that suggests that we need data on -- if we're considering buffers, what Dr. Ginsberg called a "recipient." Was that what the word was? So either you have a buffer under the plaything or you have bare soil there, especially in a backyard situation.

So either one of those is going to receive the dripping stuff from the playground equipment. Which one will create a greater hazard to the child? Will a child get more from a buffer that received the stuff from the native dirt that's received the stuff.

So I guess to answer that first question, you'd have to study both the kind of native soil that would be under playground equipment in people's backyards and you'd have to study the buffering material and see which one picks up and carries the

arsenic and chromium more. Or what's the data on how much the arsenic and chromium those materials pick up and carry.

DR. ROBERTS: Whether, in fact, it is a barrier to exposure or not.

DR. MORRY: Yes.

DR. ROBERTS: Dr. Smith.

DR. SMITH: This thought hadn't occurred to me before. But if we're actually wondering about collecting data for the purposes of maybe making recommendations of one buffering material over another for the purpose of perhaps it may be less likely to contribute to exposure, then I would just urge you to talk very carefully with your colleagues at Consumer Products Safety Commission. Because the first and foremost concern with buffering material is protection of the child from falling. That's going to be the primary consideration in selecting a buffering material. Once they're equal in that regard, perhaps you could get into a discussion of that.

DR. ROBERTS: Dr. Aviado.

MS. AVIADO: I would like to clarify. Our intent is not to work with CPSC to help specify buffering materials. They have done quite a lot of work on that. As you know, they have their

handbook for playground safety, and it seems to be there purview. It's more in terms of this assessment, this child, playground, if we need to include those scenarios. Thank you.

DR. ROBERTS: Dr. Ginsberg.

DR. GINSBERG: As the person responsible for writing this up, I'd just like to ask Dr. Morry if you can recommend a study design of some kind just to get us in the direction of the native soil versus buffering material and which one would give you more exposure. Can you help at all?

DR. MORRY: You mean just briefly?

DR. GINSBERG: What would you do in the filed if you had to test that?

DR. MORRY: I think you'd have to go in the field under, you know, playground equipment that's been there for a while and sample both from playground equipment that has buffering material under it and playground material that has native backyard soil under it. Take samples in the area where it drips onto the substrate and see how much arsenic is in the samples.

DR. GINSBERG: The one variable in there that may be hard to compare across two different playscapes is that they may have different propensity to leach. Given that.

DR. MORRY: Yeah, as you said, you know, the buffering materials have the disadvantage that a child would like to pick those up and put them in their mouth; where they wouldn't have the same propensity to pick up a handful of soil and put it in their mouth. I guess you have to have some data before you can begin to make any statement at all.

DR. ROBERTS: It might be fair game for a field study where you put different coatings over the ground and you run water off some standardized CCA surfaces or something like that to see what extent it is adsorbed to the buffering material versus penetrates through to the soil and that sort of thing.

Any other comments or suggestions on this particular question from the Panel?

Dr. Vu, have we given you --

DR. VU: Yes. Thank you.

DR. ROBERTS: Could you read Question 15? I've been waiting to say that for a long time.

MS. AVIADO: With great pleasure. The question deals with the coatings, their effectiveness at reducing the leaching of the CCA compounds from treated wood. The Panel is asked to comment as to whether the stains, sealants, or other coating

material should be recommended as a mitigation measure to reduce exposure to arsenic and chromium compounds from CCA-treated wood. And if so, can the Panel comment on the most appropriate way for the Agency to recommend effective coating materials when the current data on the long-term performance are limited and sometimes inconsistent, and should the Agency specify a time interval for the reapplication of the selected coating materials. Also, can the Panel make recommendations for addition studies?

DR. ROBERTS: I think Dr. Solo-Gabriele is going to lead off on this one.

DR. SOLO-GABRIELE: We had Presentation No. 4, underscore 4, was the one. Is that 4?

We looked at the data pretty extensively and came up with some tables we wanted to share with you.

In evaluating the coating data, I just wanted to emphasize that we have treated versus untreated wood. Treated meaning that it's CCA treated; untreated meaning that it's virgin wood, no pressure-treatment chemical added to it. And we also have coated versus uncoated. Both treated and untreated wood can be coated or it can be uncoated. And coatings is what we're discussing.

I want to emphasize that the studies that were available, we

separated them into three categories. They focus either on dislodgeable arsenic, wipes, hand wipes or Kimwipes-type studies. We also separated it into leaching. Coating studies that evaluated the efficacy of these coatings to minimize leaching to soil located below a structure. And then there were related studies that were not designed specifically to look at either the effect of the coating on dislodgeable arsenic or leaching, but had some relevant information that was worthwhile to discuss.

Also, there were different study designs. Some of them were laboratory based. Some of them were controlled field studies. I want to emphasize that the laboratory-based studies and the controlled field studies had no wear and tear component in them. So we could not evaluate the impact of wear and tear. And then there was limited work on evaluated coatings under real world situations.

The first set of data focused primarily on dislodgeable. We have Stillwell data from 1998, four matched boards he look looked polyurethane, Latex, and Spar varnish. He had data for before the coating was applied and then immediately after and then after a certain amount of time. And from this data it's obvious that the coatings significantly decreased the amount of dislodgeable

arsenic from the wood.

The additional time in Stillwell's study was one year after the application of the coating. It's important to emphasize that this study does not consider where. And, also, there's the issue of temporal control. But given the large decreases in dislodgeable arsenic, we don't think that's a critical problem.

And, also, it's important to keep in mind that there were aesthetic problems with the spar varnish after the one year that was noticed.

There's also the SCS study in 1998, again, looking at boards. It was a laboratory based study. Three different coatings were evaluated. They included a red stain which, to my understanding, was an oil-based stain. The 3M sealant was a polyurethane is my understanding. And then there was a water repellant, Osmose water repellant, that was added as part of the formulation of the CCA chemical and it was added during treatment rather than after the fact.

And the results from the SCS study were more variable. And what we did see is for the polyurethane sealant there was a noticeable decrease in the amount of arsenic, dislodgeable arsenic. However, we did not see that decrease for the oil-based stain in the

study nor for the water repellent that was included as part of the treatment process.

The next study was the California Department of Health Services, 1987. This is the only study which simulated real world applications or evaluated real world. It included a pier and a play set. The coatings that were evaluated included a polyurethane and an oil-based stain. In both cases, significant decreases, actually, very significant in the case of polyurethane, were observed after the coating were applied.

Again, these structures were then resampled two years later. And, again, the efficacy of the coating is still evident as observed from still low levels of dislodgeable arsenic.

Then we have the Consumer Products Safety Commission study of 1990. This was performed on boards, primarily a laboratory base study. It looked at oils, stain, and a repellant. The results from this study were inconclusive. But if you look at the data before the coating, they have 27 plus or mine 22. The standard deviation is almost the same size as the average, almost 100 percent of the average. They had issues associated with the variability in duplication of the control. So it was very difficult to interpret the results from the coatings.

But what we see from this data is we see some consistencies here. We see polyurethane showing up. It shows up in the Stillwell study, the SCS study, and, also, the California study. In all three cases it performed well. There's also evidence to indicate that the Latex works well. And we have some variable results on the oil-based stain.

Gary wanted to present some additional observations from the SCS study.

DR. SMITH: What Helena just showed was from the SCS study was Kimwipes of the uncoated and the coated and that showed a drop from 15 micrograms per hundred centimeters squared down to 6. That was for the Kimwipes swipe. This is from the hand-wipe results from that same study. And you can see in the uncoated condition there's quite a bit of variability which is greatly reduced when the wood was polyurethane coated and immediately thereafter swiped with the hand. And, also, the results are about tenfold lower in this case.

So just as another point of reference from that study showing the efficacy of polyurethane.

DR. SOLO-GABRIELE: And there was another slide.

DR. SMITH: This is again the Kimwipes results which we

showed in the table. You can see, again, the results tend to hang lower with the coated. But for some reason with the Kimwipes, the results weren't quite as dramatic as with the hand swipe, which we don't have a good explanation for. But the tend was the same in both.

DR. SOLO-GABRIELE: The next set of studies, which we have much more limited information, was the efficacy of the coatings on reducing the leachable arsenic. There was one study Cooper, et al., which was not included in the EPA summary. But Andy had a copy of it, happened to bring a copy of it with him.

In the Cooper study, there two sample types evaluated, fences and decks. And this was controlled conditions. It does not simulate the effects of wear. But in this study, Thompson's water seal was evaluated where the wood was treated and the Thompson's water seal was added after the treatment process.

In addition to that, there was a water repellent that was included as part of the treatment solution for both the fence and the decks. For the Thompson's water seal, the Thompson's water seal was the only one that the author considers to have observed a considerable reduction in the amount of leachable arsenic. As you can see, this reduction is observed not only from zero to four

months, but also at the two-year mark. The particular study was well designed and includes the proper controls.

The related studies, next slide, include Riedel's study, where the author has evaluated dislodgeable arsenic for various playgrounds. I believe 10 playgrounds were evaluated. Some were coated; some were not coated.

Myself and my colleagues have slightly different opinions about this. Andy may want to add to this.

In my opinion, I believe there were too many variables between playgrounds, for example, the documentation of the retention levels, the frequency of painting, the amount of wear on each of the playgrounds. So that when you compare, if you cluster the coated playgrounds with the uncoated playgrounds, there were just so much confounding factors that you couldn't really make a good comparison.

Andy, do you want to add to that? I know that you did a different analysis.

DR. SMITH: Well, I basically viewed it as a cross-sectional study with all the faults that we always think of when we think of cross-sectional epidemiological studies. But it is a snapshot of the real world. So if you take the average dislodgeable

measurement from the playscapes that actually were confirmed to not have any sort of treatment to them and compared it against the four that were treated, and they didn't additionally say "treated," but a long time ago. There was about a 70-percent difference.

But you're right. There are all those limitations with it so I consider additional information that is an indication that stains may be useful, but it's hard to know what to make of it.

DR. SOLO-GABRIELE: So even with all the confounding factors, there appears to be a reduction.

DR. SMITH: But there was a lot of variability.

DR. SOLO-GABRIELE: The last related study is Lebow and Evans in 1999, which is a laboratory based study where the were evaluating the effects of a prestain and acrylic polymer with iron oxide. It was an interesting idea, but it's not something that is commercially used. But even in this case, they were able to observe some, not as effective as a polyurethane, for example, but some decrease in the leachable arsenic concentrations.

As far as our conclusions, we find that the data support that coating reduce dislodgeable and leachable arsenic. And we find that the reduction can be anywhere from 70 to 95 percent across several, but not all, the studies. There were no studies that looked

the at both dislodgeable and leachable arsenic together.

There was not a clear coating that was identified as being the best; however, the best evidence we do have is for polyurethane. More data is needed to evaluate the efficacy of different types of brands and coatings.

Our recommendations are, therefore, separate into two categories. One is associated with future studies. And as far as future studies are concerned, we need more data to evaluate the efficacy of different types of brands and coatings.

The study should evaluate both dislodgeable and leachable arsenic because both of those represent different exposure pathways.

We, also, need to better evaluate the effect of wear and durability for the coatings. And we, also, need to provide careful consideration for the experimental design and including the proper controls.

And the second section of the recommendation is informing the public. I would consider that at this time there is sufficient to evidence to indicate that we need to inform the public of the potential benefit associated with the coating.

Right now we have some data to support polyurethane.

However, there also is data suggesting that others, such as the acrylic Latex water sealant applied after treatment and the oil-based stains may be helpful.

We find that the recommendation for the coatings is consistent with the industry recommendation. The reason the industry recommends these coatings is more from the aesthetic points of view rather than from a leaching or dislodgeable arsenic point of view; but at least it's consistent.

And one of the recommendations that I thought that my colleagues didn't necessarily concur with is that I thought that perhaps recommending a stain or a coating that was colored or visible, especially given the fact that we don't have data to look at the impact of wear. And there's a playground that my daughter went to at a birthday party. It's a very brightly painted playground. It's CCA. But in certain areas, the paint has been worn off way down, and you can see the green CCA underneath. And the playground is beautiful except for these wear spots. And I think that the color was a very visual indication of wear. Additional paint or coatings should be added, especially in light of the fact we don't have much data on wear and tear, the ability or durability of these coatings on wear and tear.

We also recommend that we should reseal once per year.

Again, another recommendation, I thought that perhaps we should reseal more than once per year in areas of excessive wear and tear. That was considered to be a little bit excessive by my other colleagues.

Also, we need more definitive information. We should provide the public with more definitive information on these other coatings once the data is available.

And that's where we left it.

DR. ROBERTS: Okay. Thank you. Very nicely organized presentation. Dr. Smith.

DR. SMITH: I just wanted to expand on one point and then raise a general comment about the public health thinking of making these recommendations.

The specific comment I want to expand upon is again the reason for emphasizing the polyurethane. It is where we have evidence from three different studies. So there's the well-controlled field study conducted by Professor Stillwell that shows 95 percent reduction out to a year.

There's the California Department of Health Services study that actually looked at a fishing pier and looked out to two years

and still, you know, 90-, 95-percent reduction in dislodgeable arsenic. So that's a real world test.

There's the SCS laboratory study which provides a third. Although since it's an internal laboratory study, only up to 17 weeks. I'm not sure that adds a whole lot of additional information over the other two. But that would be the emphasis of it.

Stillwell's data are very persuasive so that's why we felt it's worth informing people about the other agents as well. But the one you can really feel strongly about is the polyurethane.

On the public health, since it's a recommendation, at least in my own mind as someone who sits in a state public health office, I want to be clear that my thinking is we're making recommendations in the spirit of reducing potential exposures, potentially deducing them quite significantly.

In our minds, there's no question there is exposure, but we really don't know how big it is. We don't know quite what the risk of it is. But we do have some to have some pretty good evidence that there is a way to substantially reduce that exposure, whatever it is.

And so we, you know, or at least I believe that there's a real argument for getting that information out there to consumers.

Because regardless of what we do with CCA wood, we have an enormous stock of it out there that there's current exposure to and there's not very good communication of that information at present.

I would have great angst if I was thinking that people were going to use the effectiveness of sealants to reducing exposure as a way managing the use of this product in the future. If one is going to do that, then you I would say that you need to strongly then consider the behavioral considerations as well. Will people apply these sealants with any sort of frequency that's needed? Will they follow the directions? And I'm not aware of any information that's on that.

I will add that we currently have a module in our annual behavioral risk factor surveillance survey, which is a random survey, that all states do in parts for the CDC. We've put in a module about pressure-treated wood to try to find out how many homes have them and when was the last time they sealed their wood and were they even aware that they're supposed to seal their wood on an annual basis as per the manufacturer's recommendations. And we should have that in six months or so.

But I would be very concerned if we were going to think of

using it as a mitigation tool. And that way, until we know something much more about behavioral response.

DR. ROBERTS: Well, or in fact, until an assessment shows need for mitigation, that sort of thing. Dr. Ginsberg.

DR. GINSBERG: Just to add one point to the great job that my colleagues did in getting this information to you.

I just think it makes intuitive sense that this should work. We're talking about creating a surface barrier on the wood to prevent the hand or the environment from contacting the pesticide that's in the wood. So on that basis, there ought to be some level of protection.

But, also, as we heard yesterday or the day before from someone from the lumber industry, who said that the use of the sealants is recommended to prevent the splitting and the cracking of the wood and that splitting and the cracking are exactly the processes that will lead to more environmental release of the pesticide. So that if we're applying something that can, number one, create a barrier from our children's hands; and, number two, can increase the longevity of the wood and increase it's patency. It's a good thing. Intuitively, it should work.

And then we have the data to -- we don't have tons of data. I

mean, we don't have all the data we'd like to have. I think we have enough data to say that, you know, on first principle is what we think should happen is in fact borne out by the data from the labs. So it makes a lot of sense.

DR. ROBERTS: Dr. Wargo.

DR. WARGO: And, intuitively, this does make sense to me as well. My only concern is not knowing what chemicals are in the sealants and where they go. And I think, Paul, yesterday made a comment about, or a question. You questioned whether or not these sealants might actually concentrate chromium or arsenic, potentially peel off and create the next lead paint problem.

DR. MUSHAK: A bolus of exposure versus small.

DR. WARGO: Those questions are lingering in my mind.

DR. ROBERTS: Just a moment. Dr. Morry and then Dr. Ginsberg.

DR. MORRY: Dave Morry, California.

We've addressed Question 15 about whether EPA should recommend or other agencies should recommend the use of this stuff. And it seems sensible to recommend it's use.

If EPA does a risk assessment for the purpose of the reregistration of this and they find that use of pressure-treated

wood in play structures represents a hazard, and following the recommendations we've made about how to do that risk assessment, should they then do another risk assessment for play structures that are built with pressure-treated wood and then coated with polyurethane as to whether those present a -- and could they do that, present a hazard.

DR. GINSBERG: Well, I have one thought.

DR. ROBERTS: The question is sort of orbiting out there. I don't know. Is it a rhetorical question, or is it -- you want to have this clarified, I guess.

DR. MORRY: Well, yeah. It's a question that I wonder what the answer is. They could make a decision based on a risk assessment for play structures without this coating. And then it's possible that these structures would be much better, much safer with the coating. So should that be part of the risk assessment for deciding whether to reregister this pesticide?

DR. ROBERTS: Dr. Edwards, do you want to fill us in on down the road?

DR. EDWARDS: Actually, I think -- we are getting a lot of questions about sealants. That's one of the reasons we brought that issue here today. We will be doing a risk assessment that

probably some of the wood will have been sealed anyway. But in terms of whether the sealant would be part of our risk assessment as a totally separate scenario, you know, what would the risks be with the sealed wood.

We could do that, and it could be part of a mitigation measure for -- not so much for the continued use of CCA, if we find that there's a problem with the CCA-treated wood, but for mitigating risks for wood that's in use and is likely going to be in use for some time. And so that's why we wanted some of your recommendations right now for what to do, what to say to the public, actually, about sealants and resealing time.

DR. ROBERTS: I'm not hearing a lot of disagreement from the panel in terms of the recommendations by the discussants. I'd like to come to closure on this quickly if we can. Dr. Chou.

DR. CHOU: I just saying if you are going to do a separate risk assessment with sealant, I think you should also take into consideration of noncompliance because not everybody will follow up the recommended procedure.

DR. ROBERTS: I'm sorry. Dr. Smith.

DR. SMITH: The one caveat that all of my colleagues and I talked about and agreed when we were looking at this that made us

nervous and which is why we wanted to really emphasize the need for expanding the data set is, you know, making these recommendations, reviewing those data that have been provided to us, none of these have been published studies yet or peer-reviewed studies. And they all have various sort of issues with them. There is some consistency there. And because of the potential health benefits, or I should say exposure reduction benefits, we feel compelled to make this. But there clearly is some concern about the status of current knowledge.

DR. ROBERTS: And our report can reflect those caveats. Dr. Ginsberg.

DR. GINSBERG: I think it's important to address the points that were raised both a couple of days ago by Dr. Mushak and today by Dr. Wargo regarding the amount that could be in the chip whether there's a bolus effect there. And I think that Dr. Mushak brought it up with regards to chipping, peeling off paint, which would be the most likely covering that would tend to do that versus an oil-based stain or even urethane, which would tend to sort of wear through and gradually lose its coating rather than actually forming a chip.

And we don't know. We don't know the answer to that. And

we're not necessarily recommending paint as the end all and be all. And if somebody did use it, it may well be that since what we're dealing with would be something that's relatively water washable because it's being leached out under acidic rain or rainfall conditions, that as that rain continues to hit this chip as it's peeling away, it would wick away is my guess rather than just build up and accumulate there. But we don't have data one way or the other on that.

DR. ROBERTS: Let's try and keep it, try not to go too far in our analysis and reexamination, although I agree it's an important point. Dr. Smith.

DR. SMITH: Very short.

DR. ROBERTS: You're going to bring us to closure on this.

DR. SMITH: I'm just going to make one more recommendation to the Agency that I will be making for them to look in the whole issue of sealants is that it's important that we actually look to see what manufacturer's recommendations are on the use of the sealants that the consumer will be reading and that we have no conflict.

And, secondly, I only know this anecdotally, but it's not an uncommon practice for people when they decide they're going to

apply their sealant, they want their deck to look nice, bright, and shiny. And they will either treat it with some sort of chemical or they'll rent the pressure washer.

And so I think we need to give some thought to that, how that plays into all that as well such as we may want to discourage that practice.

DR. ROBERTS: Dr. Vu, have we managed to provide you with some clear feedback on this question?

DR. VU: My colleagues nod their heads. Yes, thank you.

DR. ROBERTS: Maybe they're nodding off.

DR. VU: I got validation from them.

DR. ROBERTS: Now, earlier, it seems like a long time ago in this process, I promised the committee that they would have the opportunity to discuss issues that were not covered in the 15 specific questions. And, actually, there are a couple of them that I've made notes during our discussions that I think that maybe we need to address.

So let me take the chairs prerogative and put these two issues in front of you, and then we'll see if anything has anything else.

One of those goes all the way back to bioavailability. But

the Agency asked use about bioavailability from soil. They did not ask us about bioavailability form dislodgeable residue. But when we think about what's likely to be more important sources of exposure, that assumption can be very important.

I think that we should probably -- I want to put that one on the table as well. The Agency has used a relative bioavailability assumption of 100 percent, not an absolute bioavailability assumption of 100 percent, but a relative assumption of hundred percent relative by availability.

One of the public commentors presented some information on a unpublished study on material described as CCA residue that indicated a much lower relative bioavailability. I'm sorry. It was a low absolute bioavailability suggestive of a low relative bioavailability, the hamster data, yes. Okay.

Do we have any advice for the Agency in terms of what to assume for relative bioavailability which is the information they need on dislodgeable residue? Dr. Mushak.

DR. MUSHAK: I'm pretty sure, and I talked to Vas about this and he agrees that until that material is characterized and how much of that is an artifact of the processing and how much it have would be still capturing, if you will, the native state of the

dislodgeable residue, he can't say.

So I think until that happens that probably the most prudent course is to assume that the arsenic at least is going to be present in relatively high potential for bioavailability.

I think part of the problem is -- if you put the hamster study aside, and, again, as Dr. Steinberg indicated, it's kind of a report within a report. We don't quite know what evidence would argue against a bioavailability simply because it's not clear what the arsenic in the dislodgeable is in terms of being mobilize in the stomach of a child eventually.

So I think there's a lots of scientific reasonableness to argue that, unless we have evidence to the contrary, to assume that the Agency should consider that it's highly bioavailability. If you want to take the tact that it's somewhere between, you know, say 80 to 100 percent or 80 to 90 percent, I think that's reasonable.

But I don't think that we can jump into the relatively unknown area of bioavailability and start tossing around dislodgeables being low bioavailability substances. I think that's inappropriate and it's not, to, me scientifically reasonable.

DR. ROBERTS: Dr. Styblo.

DR. STYBLO: One more argument for sort of disregarding

this particular study. I was talking to Vas after his presentation, and he mentioned one interesting issue which is that this particular extract, or whatever it was, contained high levels of selenium. Vas had published paper this or last year that showed coexposure to arsenate, inorganic arsenic and selenium solenoid would end up with a greater amount of arsenic being excreted in bile in the form of solonolglutathyon (ph) arsenide, which means that the final volume bioavailability would be greatly underestimated. He obviously forgot to mention this issue during this presentation.

DR. ROBERTS: Let me add my reservations from yet a different tack. And that is as somebody who has spent quite a bit of time thinking about and working with models for bioavailability. I have some reservations about the hamster. The coprophagia, in fact, demonstrates in this study, I think, is a problem. I think that there are some other issues about whether the absorption and excretion behavior of the hamster is similar to humans. So I agree with your comments. And I have some additional reservations about the model itself. Dr. Ginsberg.

DR. GINSBERG: The California Department of Health Services as part of their mid 1980s work on playscapes, not part of their report though, there is an addendum data set that they sent to

me. And unfortunately, I didn't bring it. But I can send it into EPA. They did do a water solubility test on the dislodgeable residue. And to the extent that water solubility of the arsenic governs its bioavailability, this is relevant.

And in that test, they poured the water solution that they rinsed, the dislodgeable was dissolved, was put into a water solution. And they poured it through Whatman filter paper. And a significant part of the chromium in the arsenic hung up on the filter paper rather than passing through it at neutral pH. But when they dropped the pH down into the three to four range, I believe, just about all of it passed through, suggesting to them that low pH solvated and disassociated whatever complexes were holding back the particulate dislodgeable material.

So they were fairly -- they also had somebody ingest some of the dislodgeable material, and it showed up in the urine. That's not anything that we could really do anything with. But it does show that an acidic pH that there would be some extra solution of it.

DR. ROBERTS: Dr. Mushak, and then maybe if we want to get away from this line.

DR. MUSHAK: I think that comparisons or the parallel

tracks of interpretation of bioaccessibility or simple solubility in bioavailability, however you index it, is simply that if you can show that simple moderate pHs that simulate anything like a human stomach mobilized materia so that the arsenic is soluble, then certainly under true bioavailability conditions defined biochemically and in vivo, that that probably is going to be highly bioavailable.

The question is always if you have a low solubility, is that applicable?

DR. ROBERTS: Let me just close by saying because I think this is an important variable in terms of exposure, I think this is an area, another fertile area, for research, focused research that could provide perhaps some useful information.

The next issue topic, if I may, and I promised Dr. Styblo, and I think it is a very reasonable thing, is to address the issue of inhalation from arsenic. And I'm going to let him make any comments he might have about that.

DR. STYBLO: I was surprised when I didn't see the issue of arsenic inhalation exposure in the background materials because issue of production of volatile gas, arsenic gas, has been around in toxicology for centuries. And the issue of biotransformation of

arsenic by microbial flora, which is present in route, and we know even on the CCA-treated wood -- I have some papers to back up my statement -- which obviously is present in soil is able to do this transformation.

I have an article in front of me which is entitled, the "Wood Preservative Chromated Copper Arsenic is a Substrate for Trimethyl Arsinebiothenthesis," published by Bill Collin, et al., all in 1984. These guys diluted CCA solution a thousand, 10,000 times and found trimethyl arsine being a product of the action of candida humica, a common fungus, on this mixture. They, also, used chips, wood chips treated with this mixture as a substrate for trimethyl arsine generation and with positive results.

I would suggest that there is a great chance that trimethyl arsine, possibly other arsines, are produced by microflora in the wood, in the soil, and even more probably in the mulch because of surface and colonization with bacteria and microorganisms like fungi.

I'm not sure at this point how important this issue is this terms of the open space kind of playground settings which produce winds and air circulation. I would suggest that it may be considered in cases like screened decks.

In my neighborhood there is a house, the owners cleaned completely his deck a couple of months after he build the house. And he used the kind of plastic glass screen with sliding doors. That could be of concern because of possible accumulation of these gases, if they, indeed, produced in this kind of space.

Another example is some people like to build storage spaces under their deck. And I know cases like that. And I know, also, kids that like to hide there playing seek and high. So, again, it is a closed space with limited ventilation. There is a possibility of this kind of exposure.

I'm not sure how this possibility, how big this possibility is. There is no, obviously, data. But I think that is something we can look at.

Also, the issue of mulch that has been discussed here. I would suggest that -- and you probably saw mulch being used in interiors, including university halls where it's being used as plant bedding. That another setting in which this risk is associated with.

DR. ROBERTS: Dr. Styblo, did you think that this would perhaps be best addressed when they do their residential and other scenarios which would be more likely to involve enclosed spaces?

DR. STYBLO: I don't think this is an issue for playgrounds unless somebody else had another opinion. I would just like to point out that trimethyl arsine intoxication in humans, including fatal cases has been described. Trimethyl arsine production from plastic mattresses as an action of fungi has been discussed in association with SIDS, which is sudden infant death syndrome.

DR. ROBERTS: Okay. We can pass that along to the Agency as a recommendation when they do their other scenarios and they'd be more likely to be involved enclosed spaces and development of gas. Dr. Kosnett.

DR. KOSNETT: Yeah. I just wanted to recognize Dr. Styblo's interesting observation in that regard.

I'm aware, also, that the action of fungi and other microorganisms can create volatile arsine; and in some cases, they've been associated with concerns about has hazardous exposures predominately in indoor settings.

Just as an historical note when they used to use arsenic-containing wall coverings in the nineteenth century that was often a concern. It should be considered another potential source of exposure that we haven't discussed. So thanks for bringing that up.

DR. ROBERTS: Let me then open it. Those were the two that I had notes on, although we had talked about other things earlier like doing studies on kids and things. I don't know if we want to get into that this evening. We can if you like. Let me open it to other panel members for issues that they think we need to provide some scientific input to the Agency with regard to their residential risk assessment. I believe Dr. Solo-Gabriele and Dr. Kissel.

DR. SOLO-GABRIELE: Just quickly, I wanted to just touch upon issue the different exposure pathways. And sometimes there's this artificial line that's set up between in-service exposure pathways versus disposal exposure pathways during disposal. And I was curious as to whether or not EPA was going to combine, look at both, the in-service pathway, exposure during in-service use and the potential cumulative effects of exposure during disposal, both indirect and direct, during disposal. If there is a separation, I think it should be all combined together.

DR. ROBERTS: Are you referring with regard to this particular exercise or later on when they do the more comprehensive.

DR. SOLO-GABRIELE: The more comprehensive.

DR. MUSHAK: That was discussed yesterday with the OSWER people.

DR. ROBERTS: Yeah. I think the answer was yes, that they would consider it.

DR. SOLO-GABRIELE: Okay. I just wanted to make sure.

DR. ROBERTS: Yes, I believe it was. Dr. Kissel.

DR. KISSEL: Yeah, I wanted to make a comment on a comment. But Harvey made the comment, and he's actually left. But I'll say it anyway.

DR. ROBERTS: We'll talk about him anyway.

DR. KISSEL: Mary Anna Thrall's mentioned biomonitoring at some point early on. And Harvey said he looked in the Gradient thing, and there were a bunch of occupational studies there and you couldn't really tell exposure by biomonitoring in those studies. So doing kids would be much harder.

I looked at that same sets of things in the Gradient document. And I found eight studies for which some conclusion about whether there was a difference associated with occupation could be found. Five of the eight were reported as significant increases in the occupational group relative to a control. A sixth doesn't say that it was. And the ratios of urinary levels range from

1.3 to 8.2 within those five studies.

There's a sixth study where I think it's just an oversight that it doesn't say whether there's a significant difference because the ratio in that last group was 10.9 between the occupational exposed and the control group. So that's six out of eight. I think it's pretty clear that you could see a difference.

The two that you couldn't see a difference where they actually made any attempt, one was measurement was taken as total arsenic instead of inorganic arsenics and you had all the swamping out of the organic species which confounds that issue.

In the other one, it isn't clear that there was actually a control group. The occupationally exposed people are said to have not had elevated levels. But my interpretation of what's there is they just compared them to that 50 microgram per gram ACGIH kind of standard which is intended to keep you from overestimating the number of people who are over exposed as opposed to underestimating the number of people who are over exposed.

It's really a high number. There's lots of people out there that have got more than background exposure. People with 50 micrograms per gram of creatinine could clearly be exposed well

above background, but they wouldn't pass that test for over exposure.

So I'm drawing exactly the opposite conclusion that he did. I think if you want to see a difference between occupationally exposed and control groups and design the experiments to produce that result, then you will see it rather clearly.

And I think, also, that the amounts of arsenic that we're talking about, and when I mentioned this earlier when we were talking about the EWG risk assessment, some of those numbers are turning out to be in the hundreds of micrograms a day of arsenic exposure. And I think that if you can't see that in urine, you ought to fire your analytical chemist.

So I think biomonitoring in children is feasible for this issue, and I think we ought to try to do it.

DR. ROBERTS: Dr. Smith.

DR. SMITH: I think at this late hour, I'm not sure I want to get into actually designing a biomonitoring study with you. But I would agree with Dr. Kissel that I do think it's feasible, but I don't think it's easily. There will probably be a need to do some dietary survey work, et cetera, to deal with that. Perhaps not. But there are ways to reduce variants by doing that. So that's something that

could be discussed.

In my own mind, I'm sort of thinking in a sort of a sequential way. In the short term to meet your needs, I guess I would like to leave the message that I would strongly, strongly, strongly, strongly, strongly, strongly encourage you to, as you're going out with your currently planned studies, to make sure that you get least adult hand data to us understand how to compare the two.

And then I'd, also, would like to just as strongly if not more so, encourage you to, since you're going to be doing these random study across the country at all these different sites, presumably they're going to be children there, so I would really like you to try to think of a way to expand to study to include actual hand-wipe sampling or some sort of sampling of kid's hands.

There's going to need to be some method developed for that because there's going to be some issues with how well you can actually remove the material, et cetera. That's something I would really like to see you work on.

Once that's incorporated into this analysis and coupled with Dr. Freeman's data and others, if we still see these sort of high numbers, then I think we do need the reality check. And I think at that point getting some sort of biomonitoring or urine study really

may make sense. But that was sort of the way I was thinking of it. There is this one source of data that I think could be very valuable to us in the short term. And then the other data I think is more in the validation stage.

DR. ROBERTS: I'm going to jump in here and then we'll take a couple of other speakers. I wanted to follow up on Dr. Kissel's suggestion because I think some kind of biomonitoring data is going to be very important in terms of -- I agree with other panel members. That's sort of the step after you've done the best job you can with a probabilistic risk assessment is see whether or not it makes sense and see whether what you predict actually takes place.

I do, also, share Dr. Smith's concern. I think it's not a trivial exercise getting these data. And the first thing you're going to have to decide is what kind of resolution do you need to see. What kind of doses are you concerned about, and are you going to be see those in urine because it really makes a difference in terms of background and you need to subtract that or to factor in dietary exposure and so forth. If you're having to do matched-meal studies and those kinds of things, that's expensive. And that has to be carefully done.

Then you're going to get into issues of what are relevant controls. And, also, what's a representative sample. How many kids do you need to get, under what kind of circumstances would constitute a representative sample to children.

And, again, I'm not arguing against doing it. And I think, ultimately, that's how we know whether or not our models work. But I think it's going to be a significant exercise.

I had Dr. Kosnett down and then Dr. Mushak.

DR. KOSNETT: Well, I hope I'm not alone in urging you to do it and consider to be probably among the highest priorities in the next steps is to do a biomonitoring study in which you measure urinary, arsenic in children who have been using these play sites.

Let's think about the things that you're interested in here. You're interested in two key issues. One is: Is there short term, as least as you posed it to us, is there short term, noncancer adverse effects. And then secondly, you're interested in carcinogenic effects.

The focus of our discussions here have been predominately on the short term, noncancer effects. And to the extent that we have talked about the magnitude of exposure that's required to produce those, to design a study that would detect that level is not

going -- you're not going to need a large study because you're going to be looking for a large difference over background.

And when you're looking for just a large difference over background, a relatively small study would have sufficient power to detect that. And given even the variabilities that might exist between certain dietary and other factors, it still shouldn't be difficult to design a study. We are having children, by virtue by this, playing on these. These areas are having levels that are associated with what we would be concerned about certain noncancer effects.

So I'm not worried about the issues of other background sources causing a considerable interference, provided that you speciate the arsenic and do other things like that.

Now, with respect to the cancer exposure, there would be perhaps a need for greater power to discern smaller increases above background. And that might -- so, you know, you might have an initial study that helps address one of the short term noncancer effects, and you might want to have a more sophisticated and larger study that would give you more power to detect the lower levels of exposure that still might be associated with the cancer risk.

I would really encourage it. I mean, a lot of effort and a lot of concern as being -- and there's been a lot of debate over these past few days about some key issues. And a lot of, I think, one of the things we have agreed on pretty consistently is what we don't know. And a lot of it has to do with the magnitude of actual interim exposure ingestion that occurs, absorption that occurs. And the best way to do is it is to do biomonitoring study in my opinion. And I would encourage you to look into that as promptly as possible.

DR. ROBERTS: Dr. Mushak.

DR. MUSHAK: Yeah. I have two recommendations with biomonitoring. And comment on a protocol you already have for the CPSC thing with the soil sampling.

Natalie and I are concerned about that aspect. But staying with the biomonitoring, it's been my experience in a number years of setting up biomonitoring studies with children in an environmental setting with toxic metals that you want to make sure that the biomonitoring not only shows that entry of the contaminant has occurred but that the uncertainty and variability in how that can be done and interpreted doesn't drive everything to the null in such a way that it becomes a substitute for modeled

intake. I think that biomonitoring is very valuable. Everybody would agree to integrate with the uptake modeling.

But if you have reasonably reliable uptake modeling that says a fair amount of stuff is going in; but we can't see it. You have to question the biomonitoring. As someone who's been involved with that with a fair amount of my career, I have no problem with that.

The second issue goes to how do you reduce being able to control for other sources of arsenic. And I come back to what I think, maybe the industry folks can help us with quite a bit, is to give us a feel for what are the tracer elements or minor components of CCA materials as they use it that would permit us to say if those show up in urine and they don't come from any other source, then you can, in fact, do the tracer approach of allocating fractions rather than trying to do these very, very complicated diet control studies. Anyone who's been involved with those knows that they're horrendously problematic.

And the business with the soil protocol for the protocol you do have, you don't have to design anything new. You just have to do something better that you have. And that is to sieve and fractionate the particles in the soil portion.

I couldn't believe that you guys are going to go ahead and do bulk soil samples because the fractions that stick on kid's hands, as Natalie indicated earlier, is well below that. So you're going to get fairly major underestimates of what the kids are ingesting if you simply look at bulk analyses. In this day and age that's impermissible both scientifically and epidemiologically.

DR. ROBERTS: Dr. Bates.

DR. BATES: I'd just like to add my voice to those who are in favor of a biomonitoring study. I personally think it's absolutely essential to confirm the models. I don't think we necessarily need to wait until the models are complete. I think we could do it now. I think it's important information which is of great need.

I also wanted to say something about I'm aware of certain arguments that come up frequently to be used against doing epidemiology studies. One of them is confounding. The other one is representativeness. And I've heard both of them put forward here. And I just want to address them briefly.

First of all, confounding. In this case confounding would refer to other sources of arsenic, and concerned has been expressed about dietary sources getting in the way. Now confounding is only

an issue if there is correlation in the exposure to the CCA arsenic and the diet. So you can postulate that children who play on decks or this play equipment might be more likely to eat fish. But on the face it, it seems unlikely. So unless there's correlation, that's not an issue. And I can't see any obvious reason why there would be correlation.

By all means, go ahead and collect the information on dietary sources in so far as you can. And that can be taken into account in the analysis. But I don't see any reason to believe, a prior anyway, that would get in the way. It should be quite possible, provided you've got two comparison groups.

If there's no correlation with any other source of arsenic exposure, you should be able to detect a difference because those other factors sort of even out between them.

And the other issue is representativeness. I don't believe we need sort of a representative study across the United States. I see this as an issue of causal inference. In other words, is there an association between exposure to CCA-treated wood and high levels of arsenic in the urine representing a higher exposure.

I think you could do that on some selected group of children in one community would give you very useful and valuable data.

And you might, particularly in that sort of situation, select a community which would seem likely to give you the highest results, a sort of worse-case situation and start there.

So anyway, I just wanted to say that about doing a biomonitoring study. I think it's really essential, and I don't believe there are arguments against it.

DR. ROBERTS: Yeah. I think that it depends on the information you're trying to get. And I agree. You would probably be best off given the fact that you probably couldn't do a very large study concentrating on situations where you think the exposure might be greatest. Otherwise, no matter what result you get, someone is always going to say, yes, but you didn't look at the kids that had the highest exposure. So I think you have to be very careful be picking that population, and not only where they live, but their activity patterns. All of those kinds of things because you're going to have to defend. If you find that there's not significant elevations in arsenic, you're going to have to defend why those kids are the worst-case kids and there's not other kids out there getting more.

And I think the issue about dietary exposure which really is an issue of noise and enormous background noise if you're going to

be looking at urinary arsenic levels, picking out what really matters in the presence of a lot of arsenic contributed by dietary sources and so forth.

I like Paul's idea about a tracer is one way to get around that, and maybe there's some other ways to do that.

DR. BATES: A tracer would have to kind of move along at the same pace the other components of the CCA. And if there was some sort of differential absorption, that wouldn't necessarily work.

DR. MUSHAK: I think that by definition a tracer sort of overlaps the toxicokinetics or the pharmacokinetics of the agent of interest. It's not enough that it shows up in the same medium or source.

DR. HOPENHAYN-RICH: I don't want to be redundant here. I know we're all tired. But having conducted a number of epidemiologic studies where urine samples were taken and urinary arsenic was used as exposure, I want to really underscore the not-so-easy task of doing this kind of study. And that if it's not really well-planned and well-conducted, you're going to end up either with a negative study that everybody is going to say, well, it's negative because you didn't control for this and this and that.

And if it's positive, you might have the same problem.

I think there's important issues of sample size. There important issues of variability. I know from a lot of studies that I've been involved with, especially at the lower range of the exposure, you can easily get a lot of variability that you're not going to easily explain. Why in a community that drinks water at 20 or 30 or 50 micrograms per liter do you find some individuals with 200 micrograms per liter in their urine and some individuals with 1 microgram.

So I think that even though confounding per se might not be an issue. If you don't have a really large sample size or you have really well controlled measured exposure of food intake, perhaps you're going to need 24-hour urine collection to account for within day variability, which is very hard to do with children.

I just don't want to go down the list right now. But I just want to make it clear that it's not trivial. And I don't think it's going to be very trivial either to find a group of kids that are clearly exposed versus kids that are not exposed at all to make the comparison. So I just want to caution on the -- you know, it's appears like at the beginning, oh, it's really easy to do this. Let's do it. It's not.

DR. ROBERTS: Dr. Francois.

DR. FRANCOIS: When I replied to Question No. 1, one of the recommendations I made was to actually go out and try to do a biomonitoring study. And that was yesterday. I'm really glad the, finally, the panel is getting excited about the idea of possibly doing this.

Perhaps combining Dr. Smith's idea of taking wipes of the kids hands and trying to get some arsenic level from those very children could be a way to go.

DR. ROBERTS: Yeah. Dr. Hopenhayn-Rich.

DR. HOPENHAYN-RICH: I just want to add one more element of importance. The laboratory that does the analysis is also really important.

DR. ROBERTS: Just to add sort of a procedural wrinkle to our discussions. For our previous questions, we had an individual that was designated to collect the comments and assemble the Panel's response. We've now dealt with three questions, the last one, of course, had generated the most vigorous discussion. We need to capture this discussion in our report.

So let me ask for a volunteer. You don't have to write down everyone's comment, but you do have to be the person who collects

written comments from those who have expressed them to compile our minutes, if you will, our discussion on this last, I think, fairly important topic. Come on. Don't make me pick somebody. Dr. Bates.

DR. BATES: I'll do it.

DR. ROBERTS: Thank you very much. I appreciate it.

DR. SMITH: I'll be more than willing to assist.

DR. ROBERTS: Dr. Bates and Dr. Smith will combine. So, please, people who have made comments, please put them in writing and be sure that they get them.

Dr. Vu.

DR. VU: Thank you, Dr. Roberts. I just want to get some clarification from the Panel.

You have recommended the Agency to go ahead and do the probabilistic risk assessment. And in doing that, certainly we are doing a predictive risk assessment to look at the typical dose that, you know, children were exposed to. And I heard some recommendations that we need to have some truth grounding.

Are these estimates realistic? They in the ballpark. And, of course, the biomonitoring is one example to find that. So we all recognize how the complexity of doing that. That really means

that you have to get pharmacokinetic model. You have to basically look at arsenic. Where is it coming from. The different source. You have to do all that and relate it to that.

So the question I have is: Do you feel that we must have that side by side where you get the predictive risk assessment to be able to do that, or we can make some decisions based on the -- and this thing can go a long with a sequential track? I'm hearing that you need to have that parallel track from some of you. But I want wasn't sure. I just want to get some sense from you all.

DR. ROBERTS: I suspect we might have some differences of opinion on this. But let's go ahead elicit those comments. Dr. Kosnett.

DR. KOSNETT: I would say if we had a choice between doing the modeling and doing the study, in terms of biological monitoring, I would do that first. I would do the biological monitoring first.

And I'd like to ask Claudia, because I have tremendous respect for you in your studies. But, you know, the way I look at it, the background level of arsenic excretion in the United States for inorganic arsenic monomethyl and dimethyl arsenic acid is approximately 10 micrograms per liter, you know, from all

sources. That's based on a large community-wide study done by David Kalman and Associates, University of Washington in the 1990s.

And we have talked about the fact that our concerns about acute exposure, the levels that you are worried about for causing nonacute noncancer effects or noncancer effects, you know, a dose that would bring these out of concern, is going to be well above that. And as such, I don't see why we require a large study or where it would be difficult to achieve relative confidence with that. To have a study of sufficient size, sufficient power, to get the power to detect the difference that you would need to get in the range of saying this represent the acute hazards within six months, is not going to require a large numbers.

Claudia, unless you think I'm off the mark. I'd like to hear.

DR. HOPENHAYN-RICH: I don't know. I don't think we should get into a lengthy discussion of this right now. I think that, first of all, the term "large numbers" is a relative term. I mean is 10, is 100 large or 500 or a thousand large. You don't have to answer me. I'm just posing it.

And I do think that there is a lot of variability. You know, the smaller the study, the more you're going have to control

everything. Do you think it's feasible to take 24-hour urines on kids? Are you going to be able to capture the kids that have, even if you expect -- if you're going to look at the NOAEL, or whatever level is of concern, are you going to make sure that you include all the kids that have certain behaviors that are riskier than others, the thumb suckers, the curious kids that play with the mulch.

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